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**Leeflang et al.**

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(45) **Date of Patent: Nov. 13, 2018**

(54) **CATHETER DEVICES AND METHODS FOR MAKING THEM**

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**Related U.S. Application Data**

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(Continued)

(51) **Int. Cl.**
***A61M 25/00*** (2006.01)
***A61M 25/01*** (2006.01)

(52) **U.S. Cl.**
CPC ..... ***A61M 25/0053*** (2013.01); ***A61M 25/005*** (2013.01); ***A61M 25/0026*** (2013.01); ***A61M 25/0028*** (2013.01); ***A61M 25/0029*** (2013.01); ***A61M 25/0045*** (2013.01); ***A61M 25/0136*** (2013.01); ***A61M 25/0147*** (2013.01); *A61M 2025/0047* (2013.01); *A61M 2025/0166* (2013.01)

(58) **Field of Classification Search**
CPC .. A61M 2025/0047; A61M 2025/0166; A61M 25/0028; A61M 25/0029; A61M 25/0045; A61M 25/0053; A61M 25/0136; A61M 25/0147
See application file for complete search history.

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*Primary Examiner* — Imani Hayman
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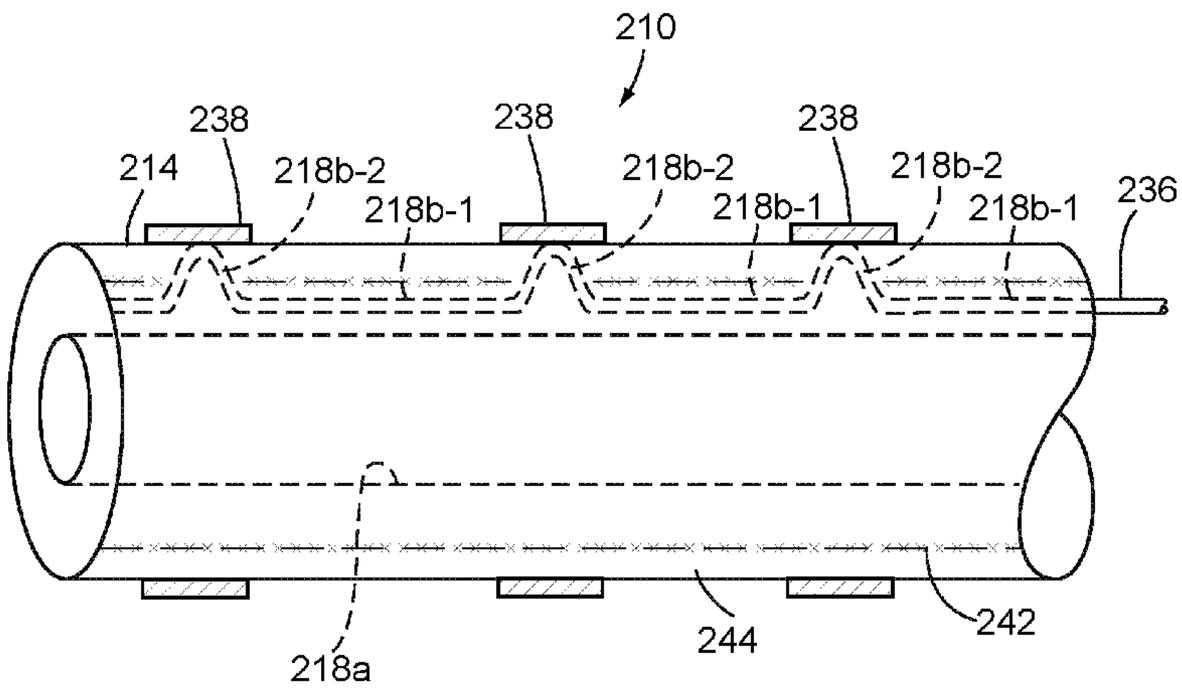
(57) **ABSTRACT**

Catheters, sheaths, or other tubular devices are provided that include a proximal end, a distal end sized for introduction into a patient's body, and a steerable distal portion. The tubular device includes a primary lumen extending between the proximal and distal ends; an auxiliary lumen adjacent the primary lumen; and one or more reinforcement members including windings extending helically along at least the distal portion, at least some of the windings passing between the primary and steering element lumens and at least some of the windings surrounding both the primary and steering element lumens. In one embodiment, a steering element is slidably disposed within the auxiliary lumen. Apparatus and methods for making such tubular devices are also provided.

**19 Claims, 10 Drawing Sheets**



**Related U.S. Application Data**

(60) Provisional application No. 62/053,188, filed on Sep. 21, 2014.

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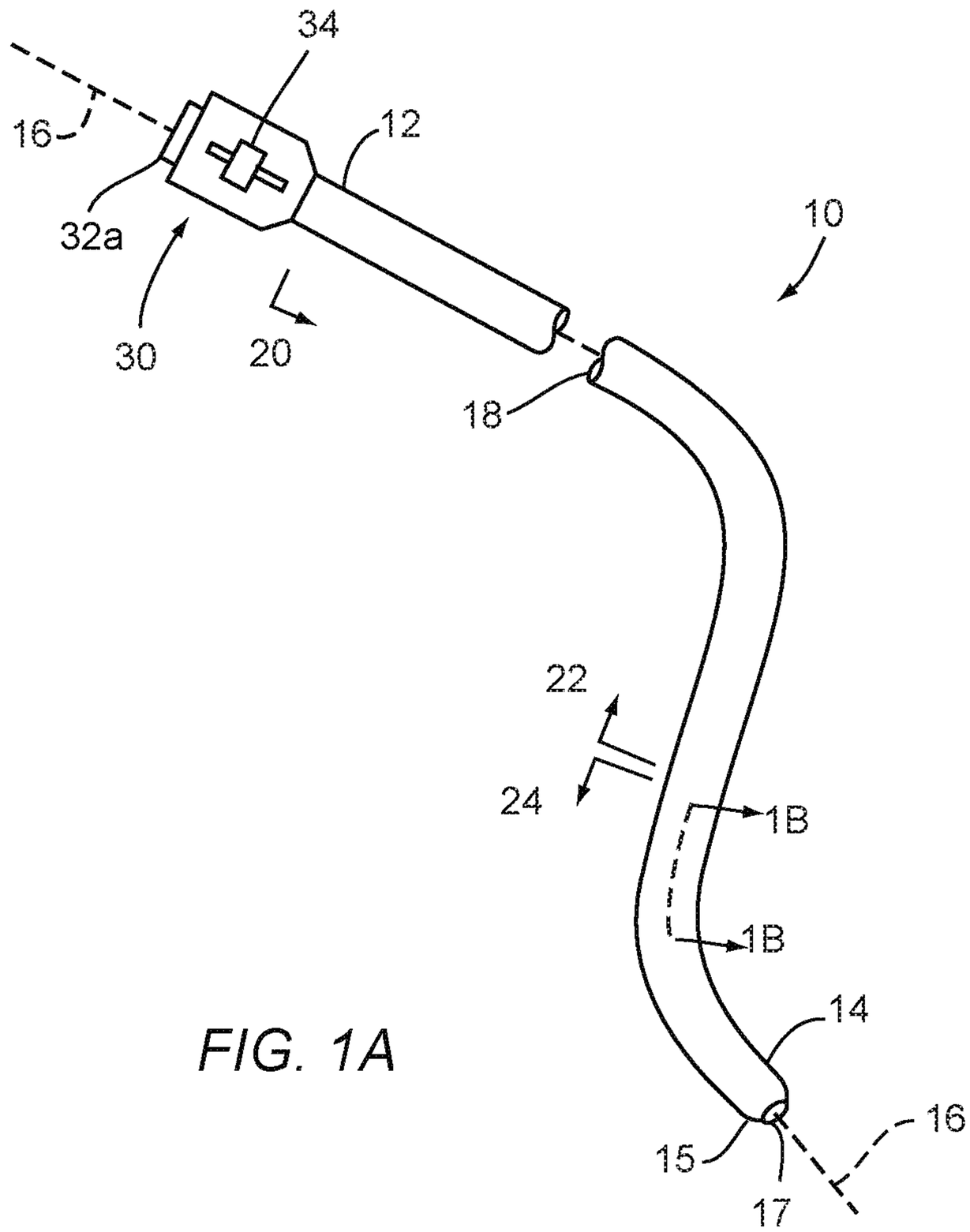



FIG. 1A

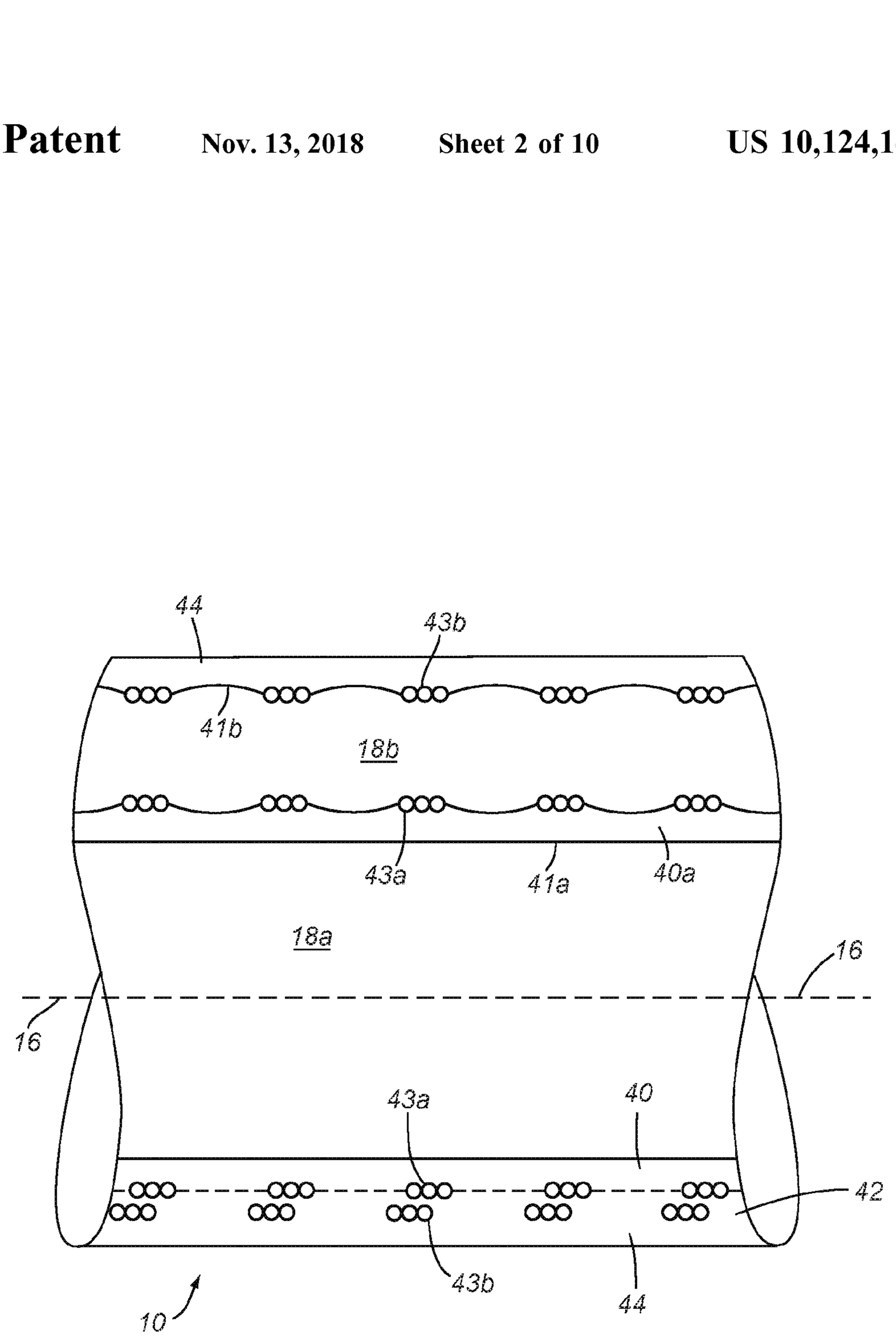



FIG. 1B

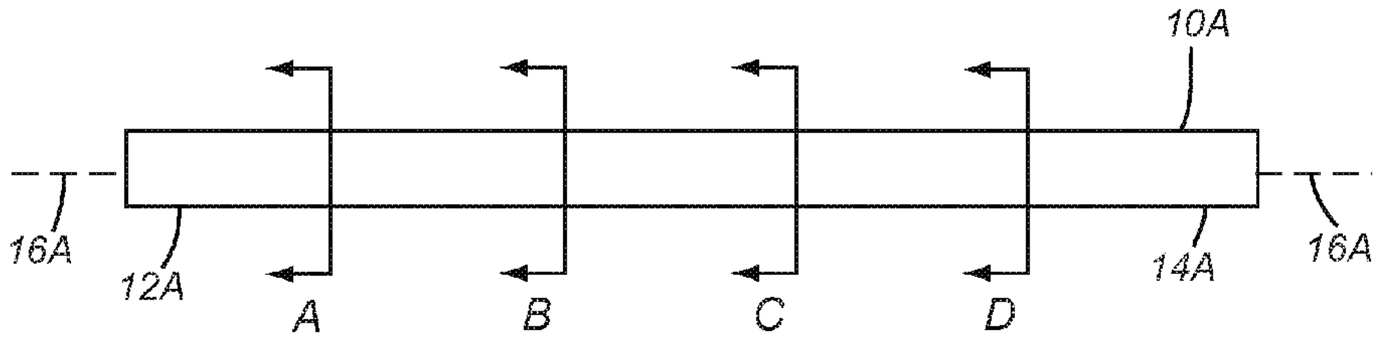

10A
16A
12A
14A
16A
A
B
C
D

FIG. 2

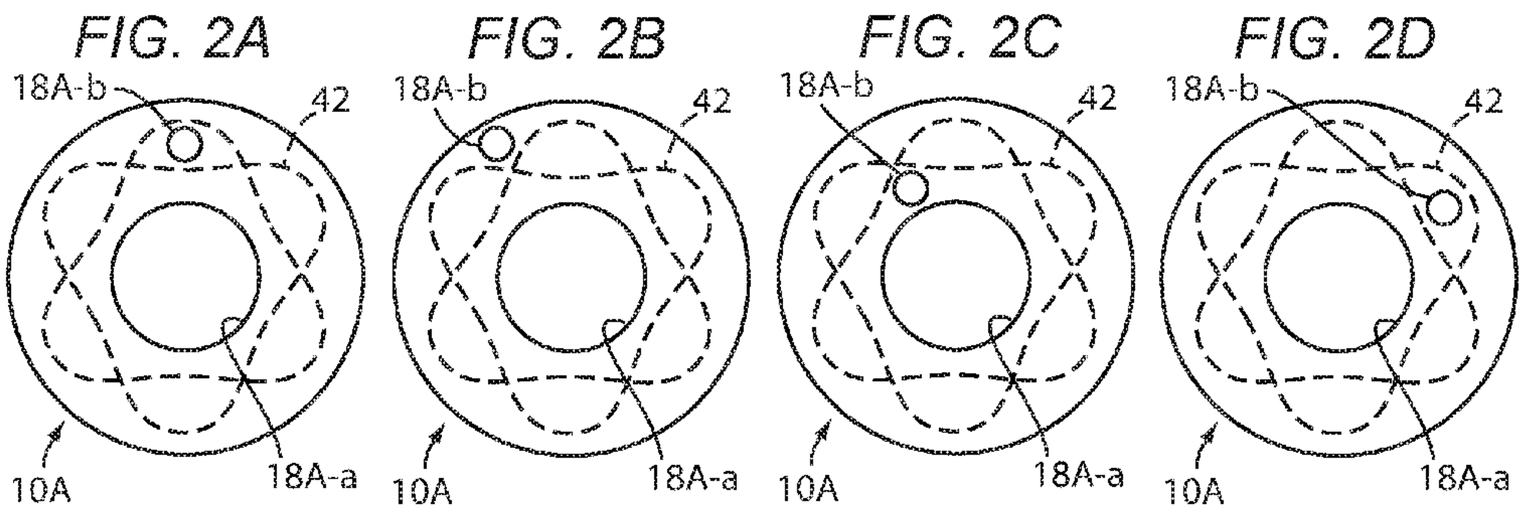


FIG. 2A
FIG. 2B
FIG. 2C
FIG. 2D
18A-b
42
10A
18A-a

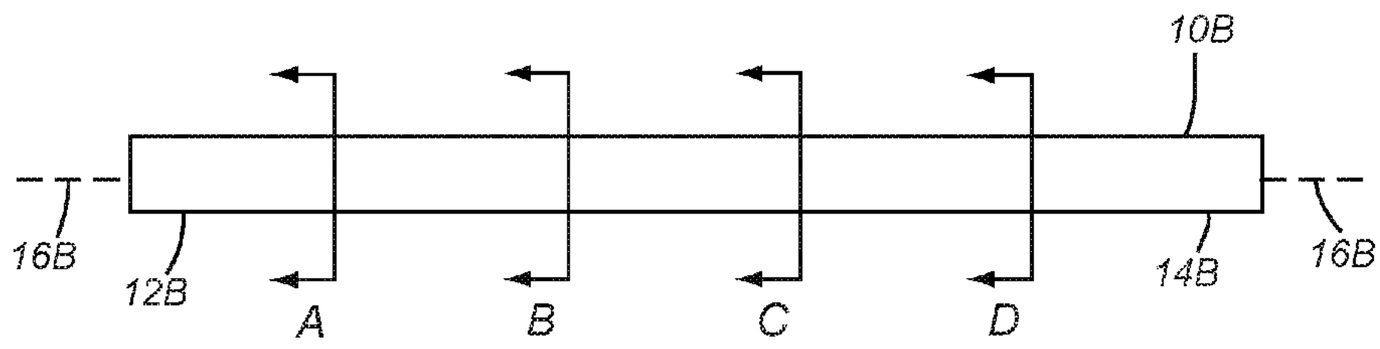

10B
16B
12B
14B
16B
A
B
C
D

FIG. 3

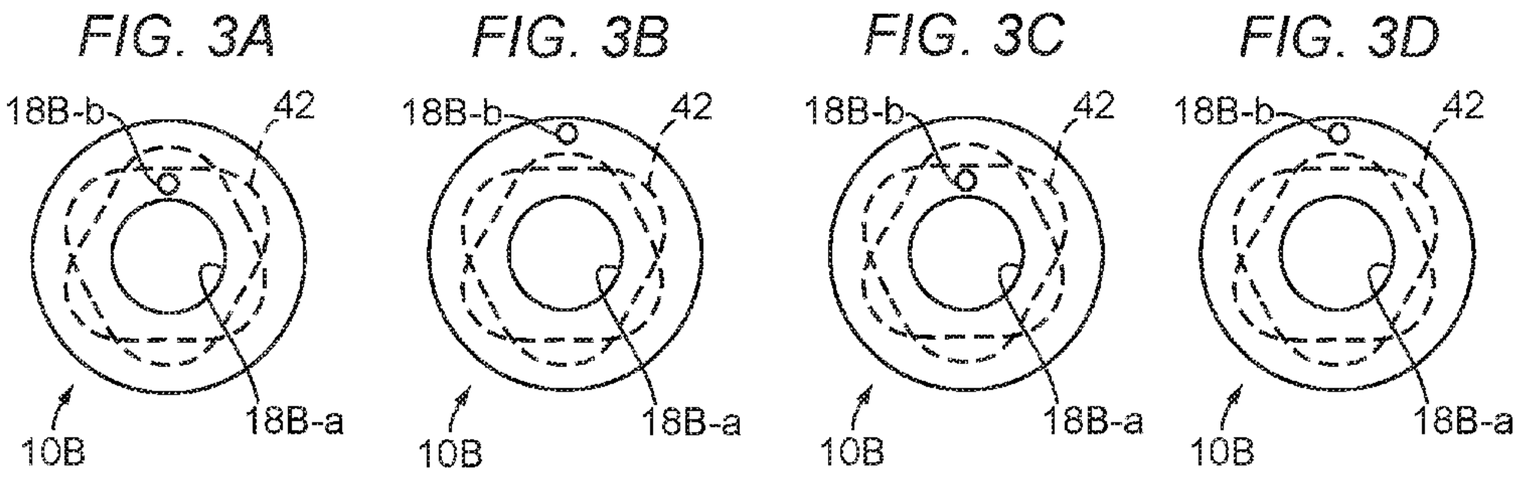


FIG. 3A
FIG. 3B
FIG. 3C
FIG. 3D
18B-b
42
10B
18B-a

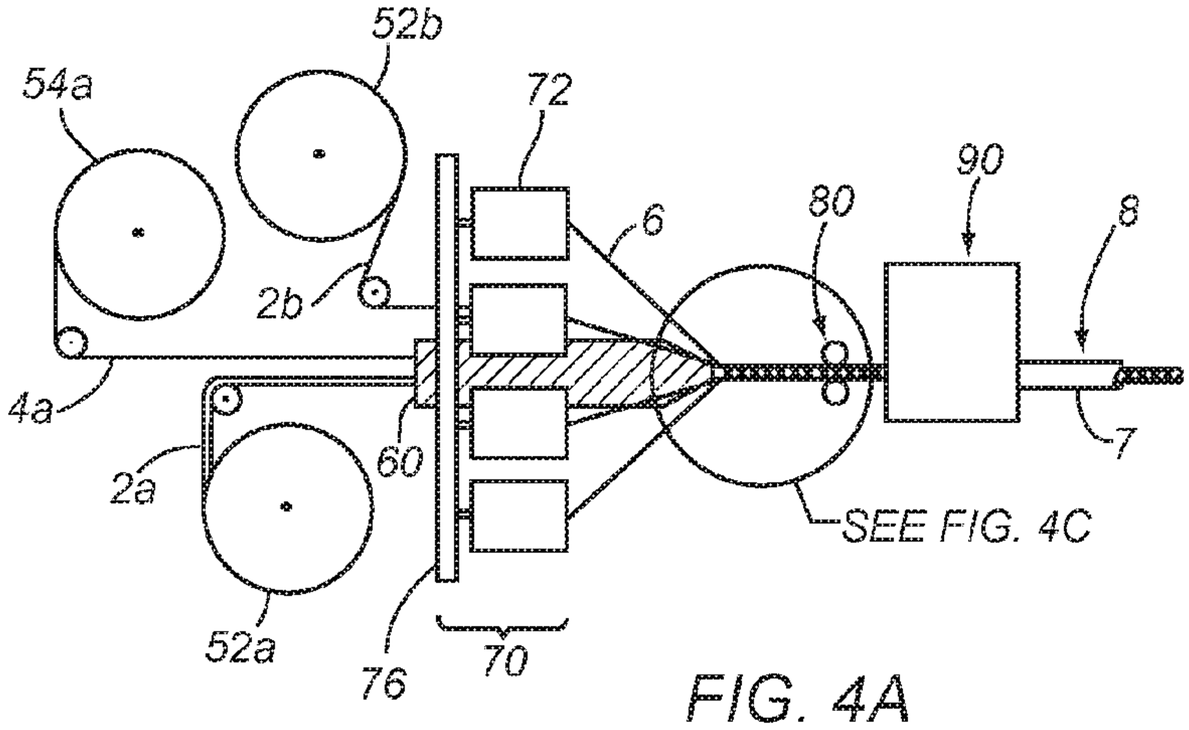



FIG. 4A

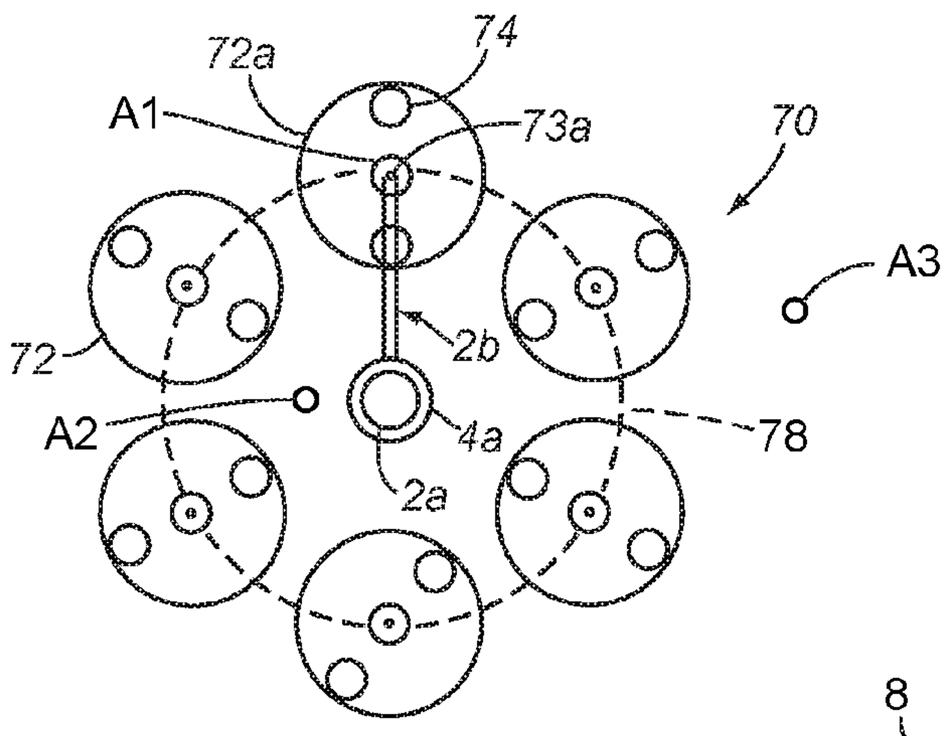



FIG. 4B

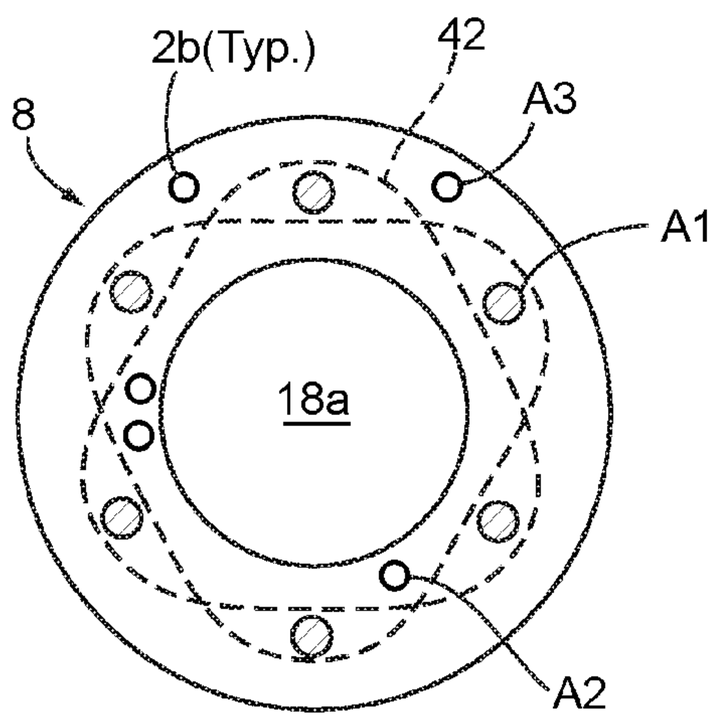
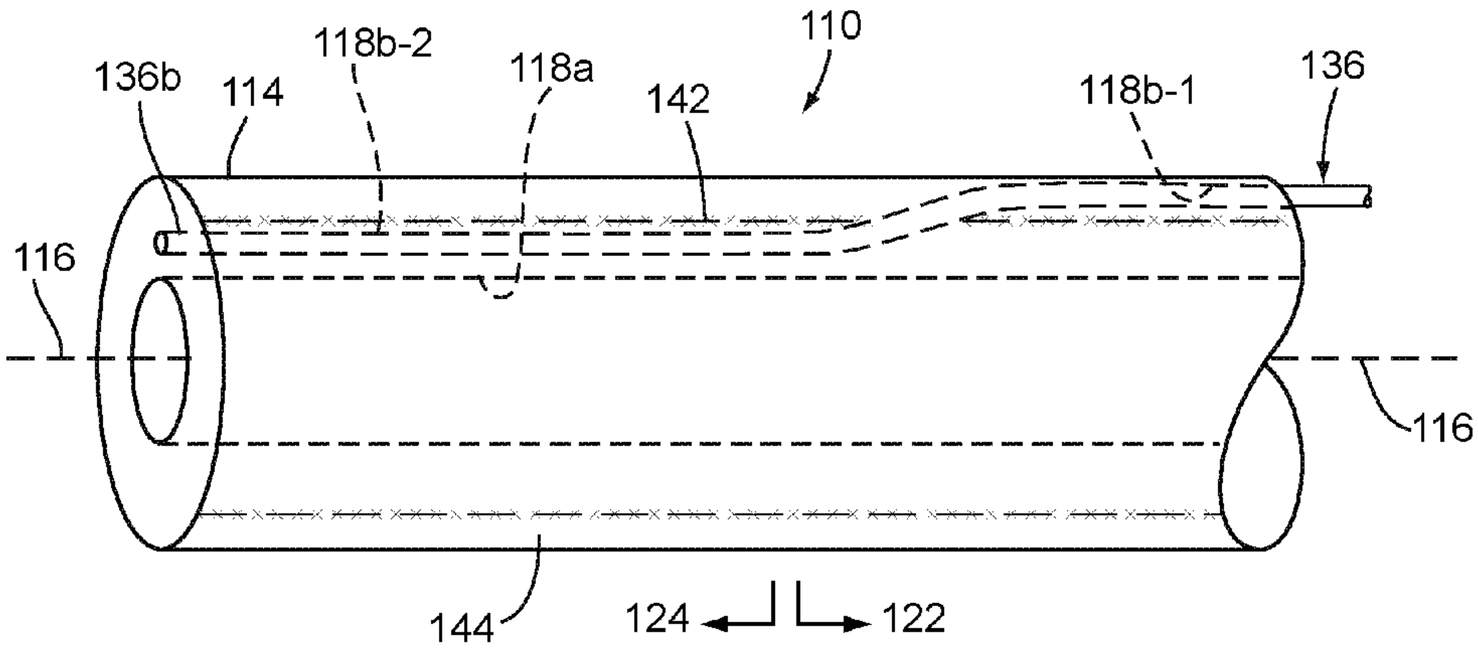



FIG. 4C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118b-1
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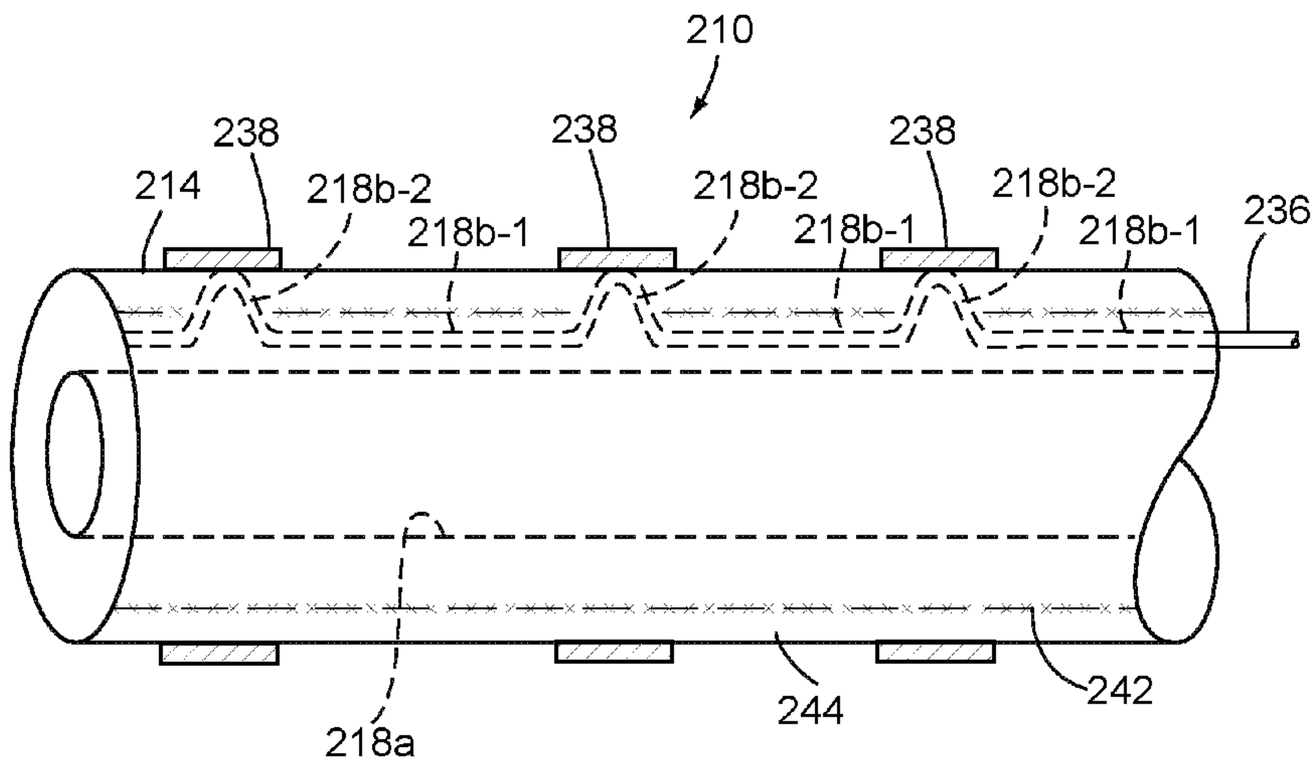
FIG. 5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238
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218b-1
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218b-1
236
218a
244
242

FIG. 6

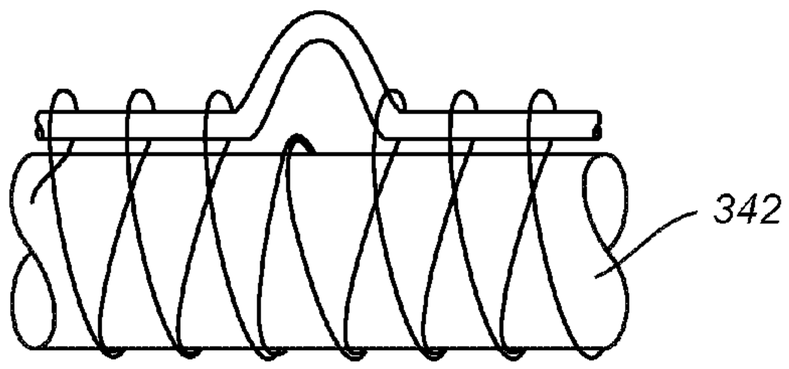


FIG. 7A

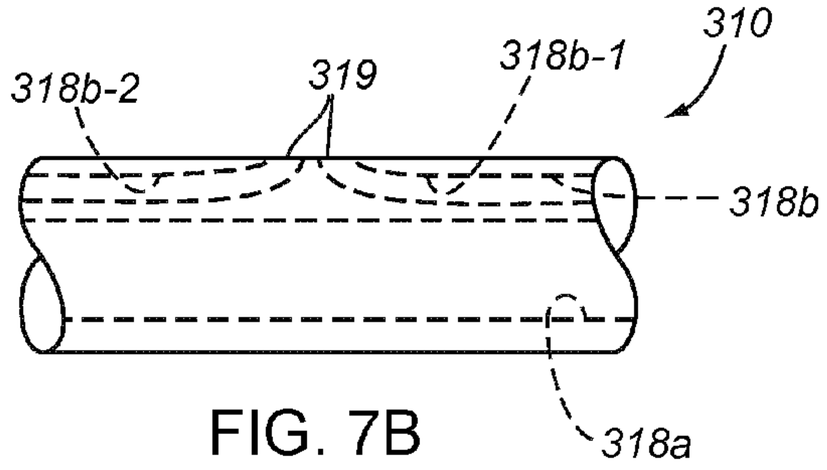


FIG. 7B

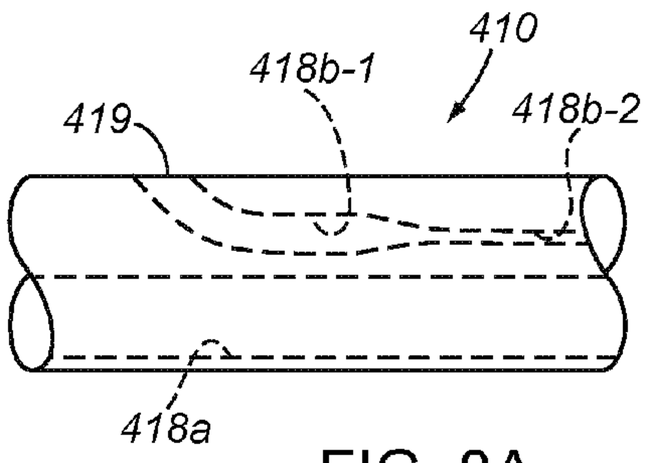


FIG. 8A

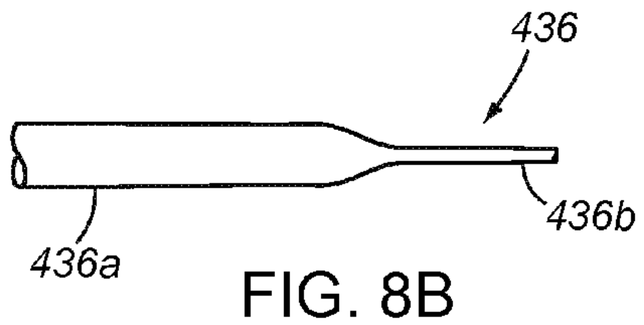


FIG. 8B

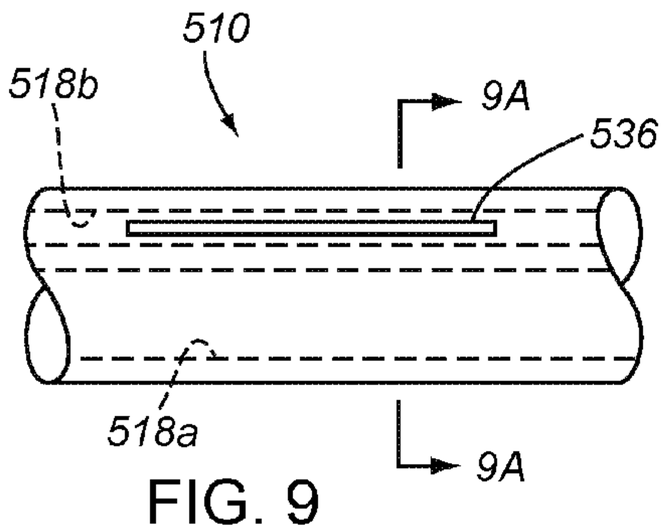


FIG. 9

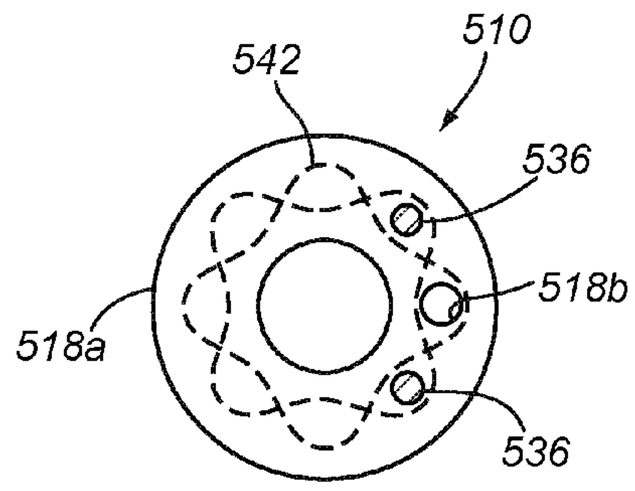


FIG. 9A

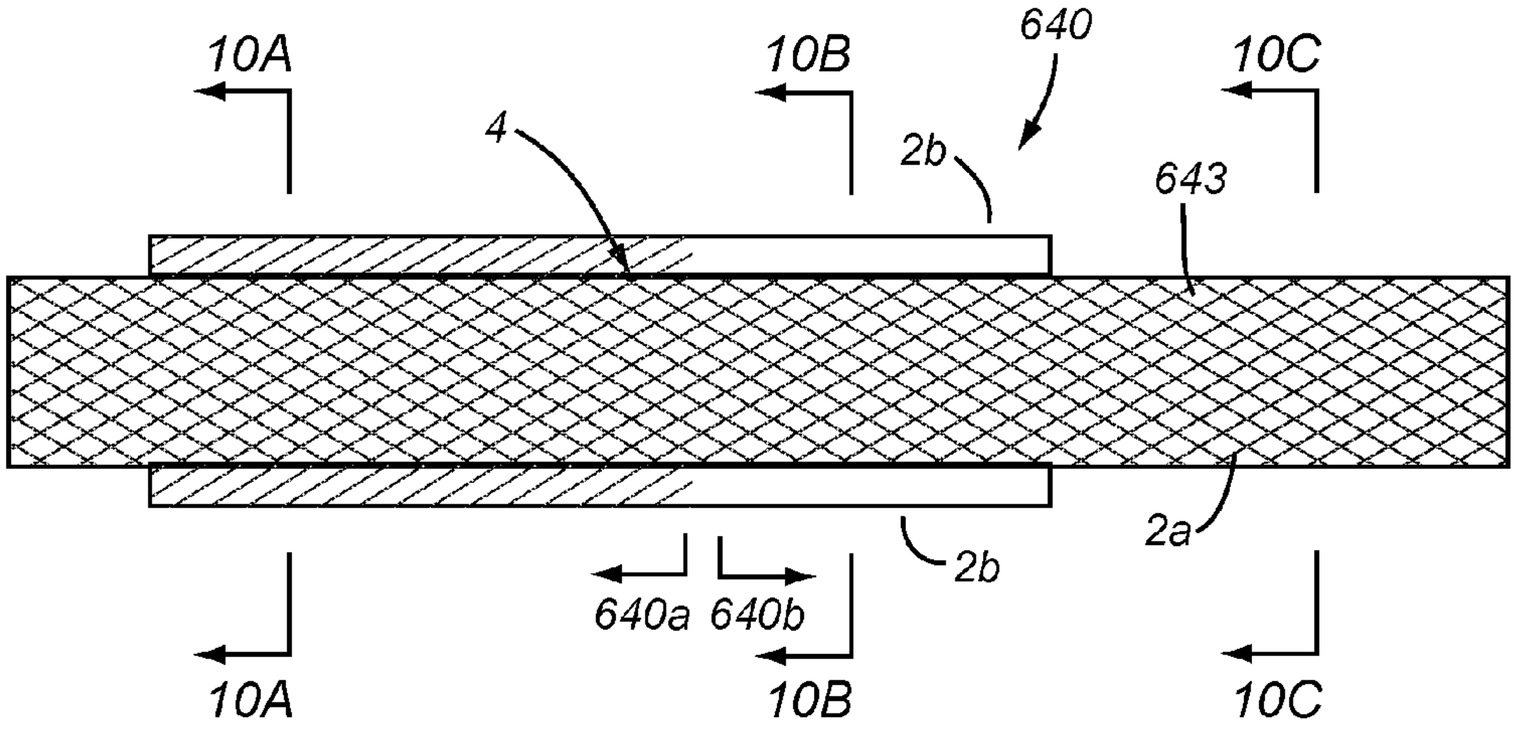


FIG. 10

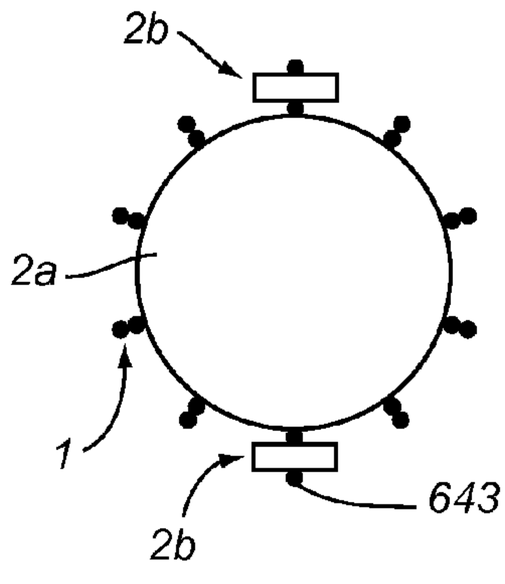


FIG. 10A

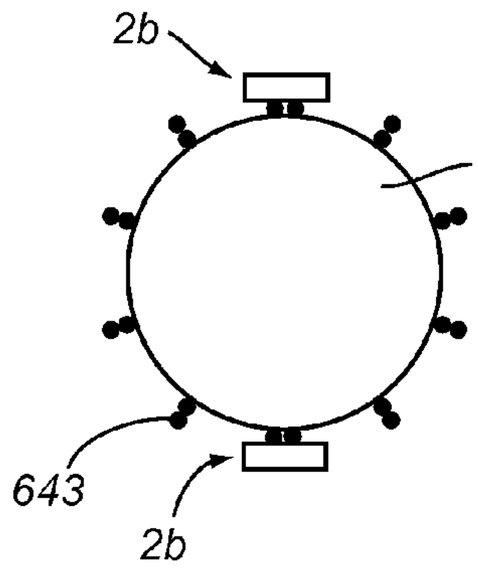


FIG. 10B

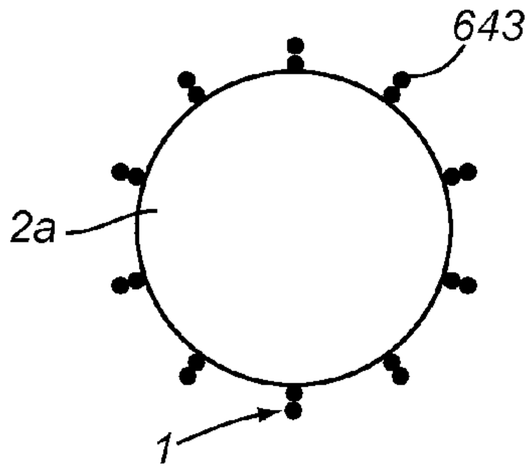


FIG. 10C

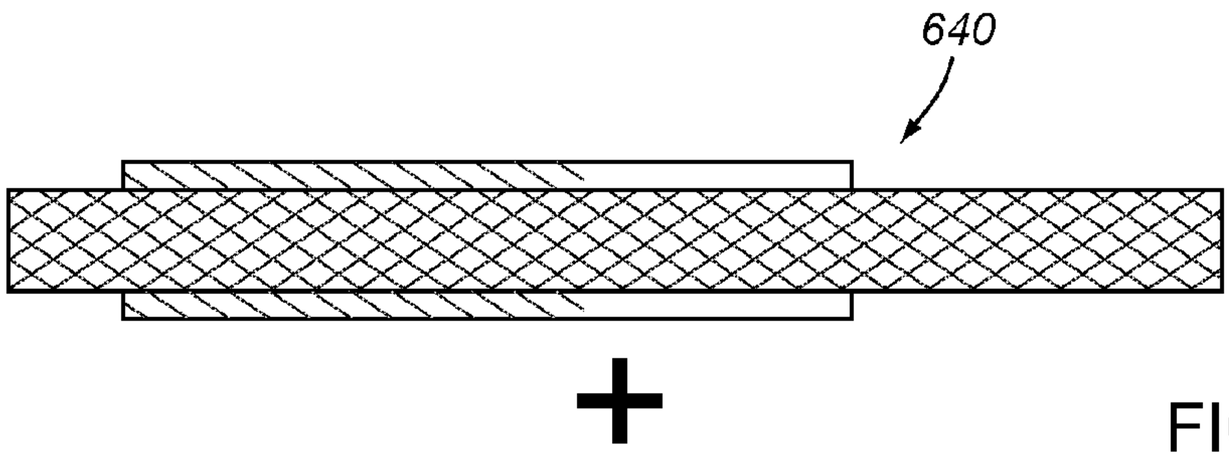


FIG. 11A

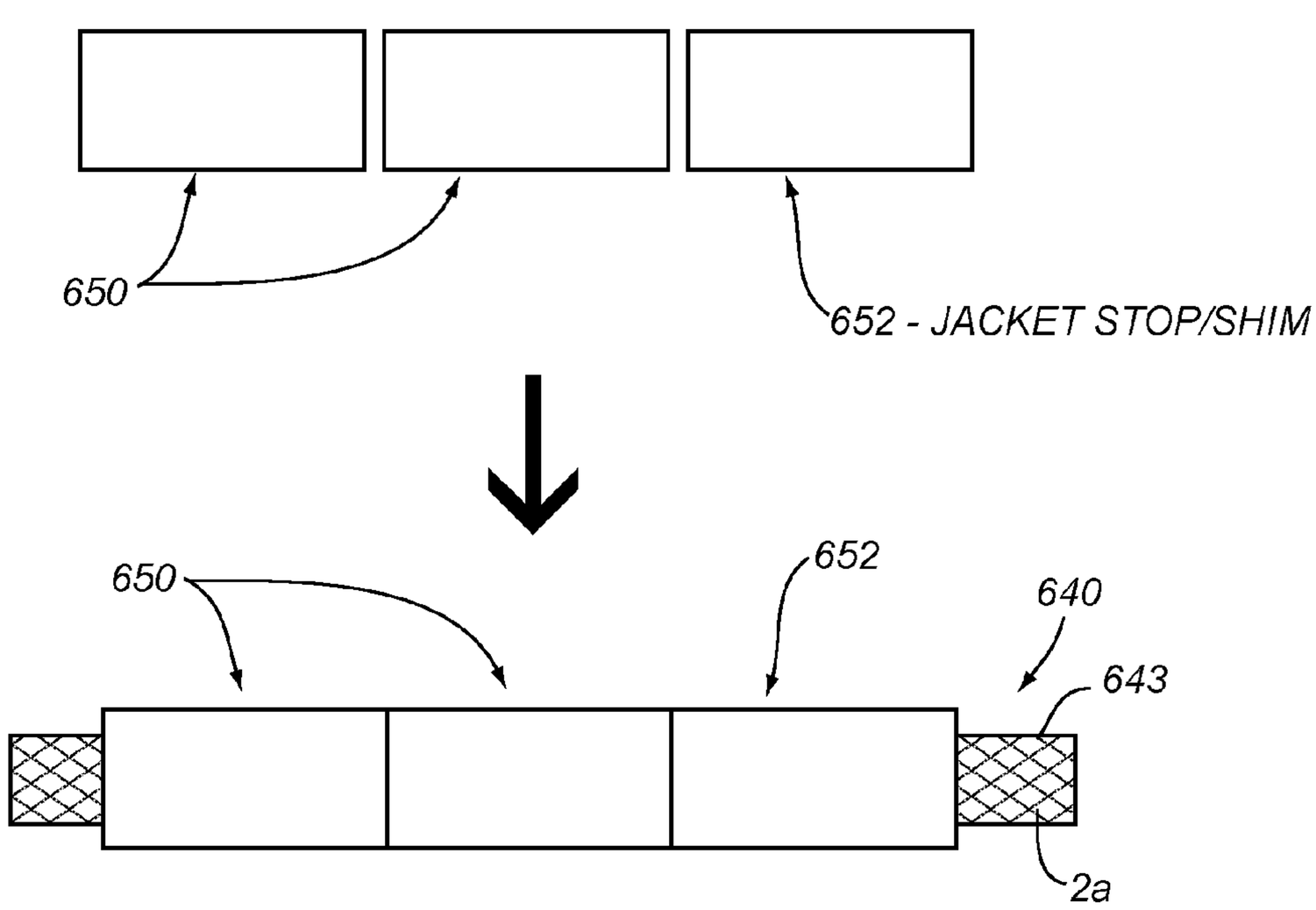


FIG. 11B

LAMINATE
& REMOVE JACKET STOP

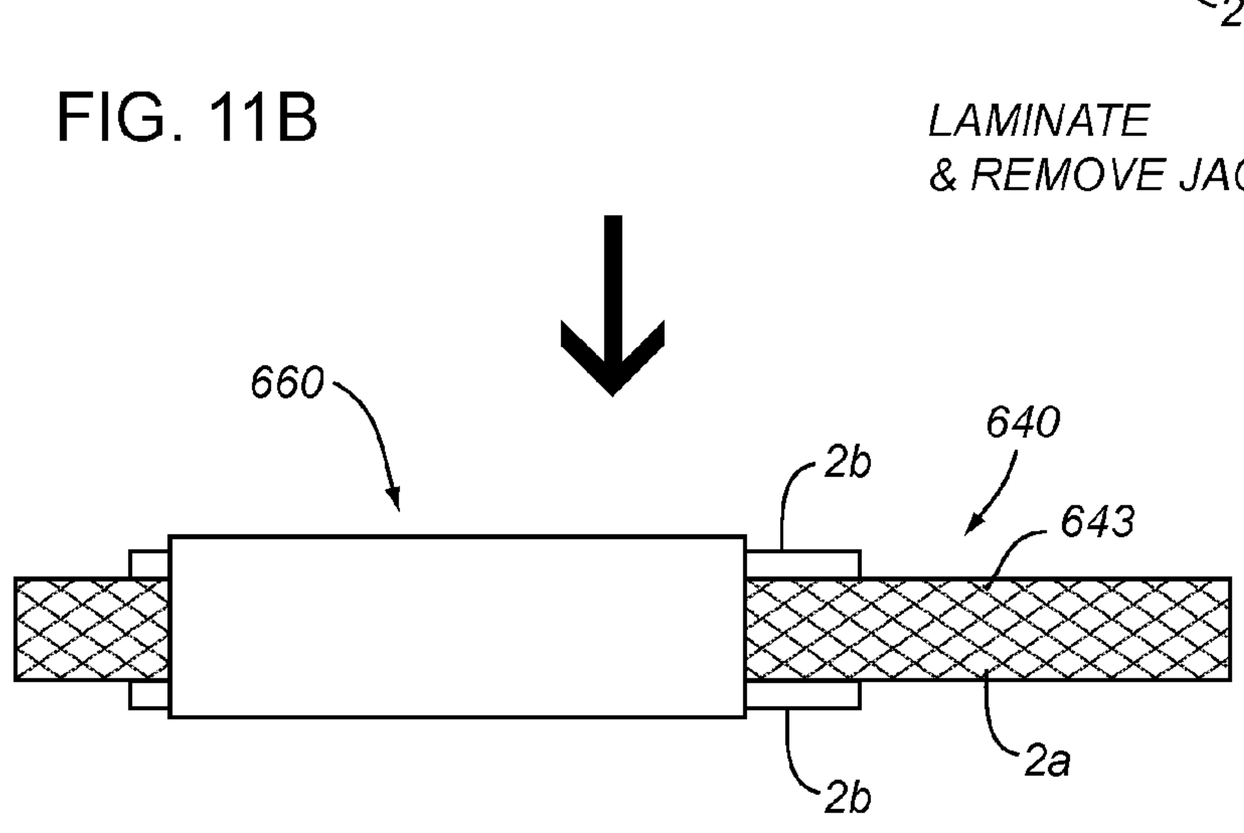


FIG. 11C

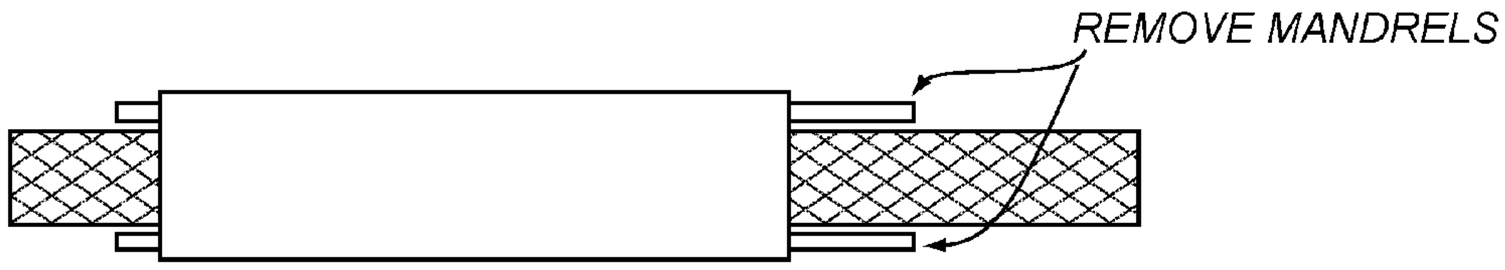


FIG. 11D

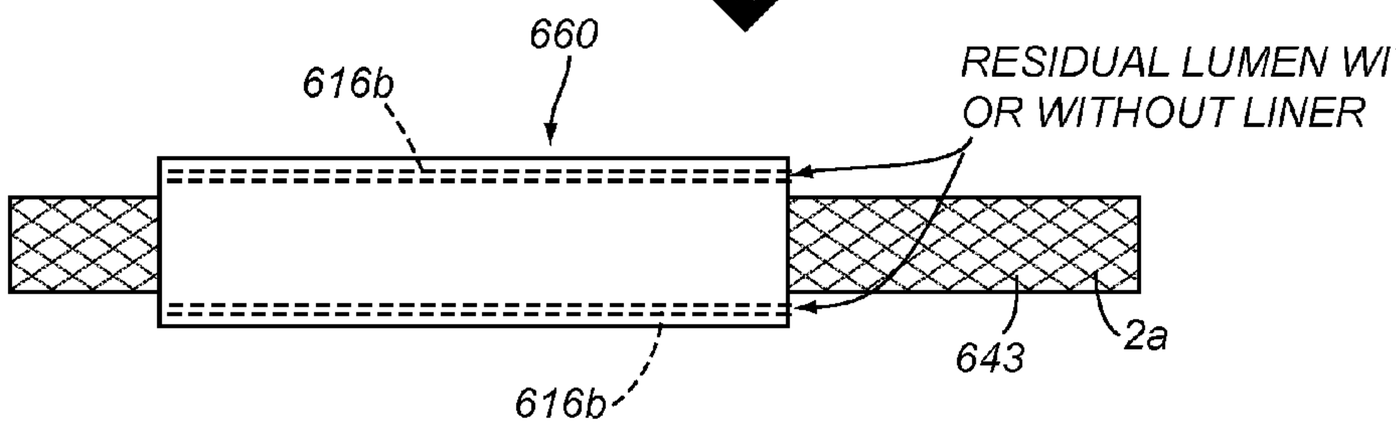


FIG. 11E

ADD PULL WIRE & TRIM BRAID

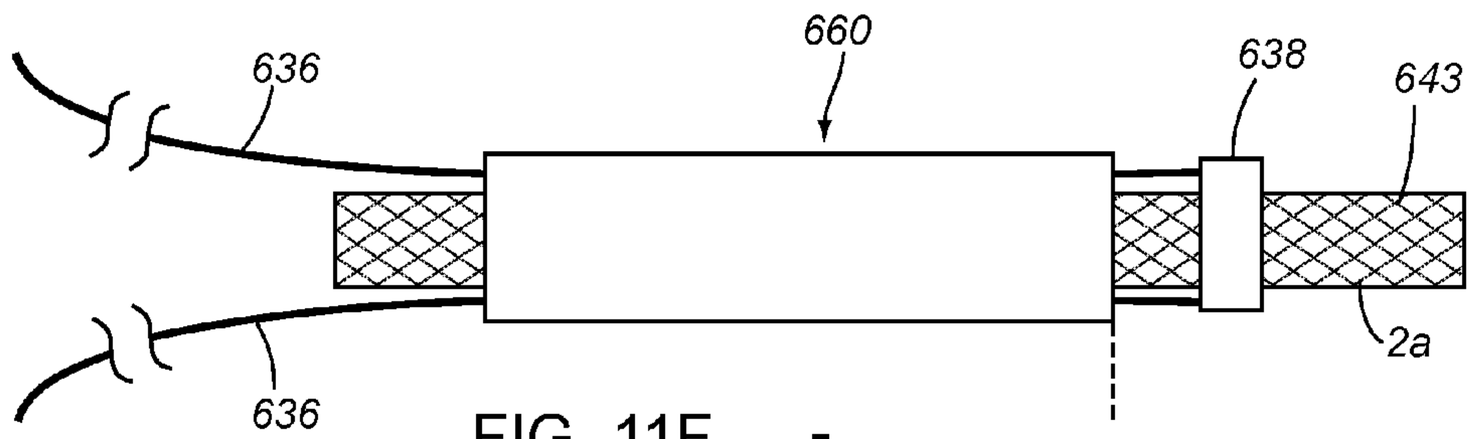


FIG. 11F

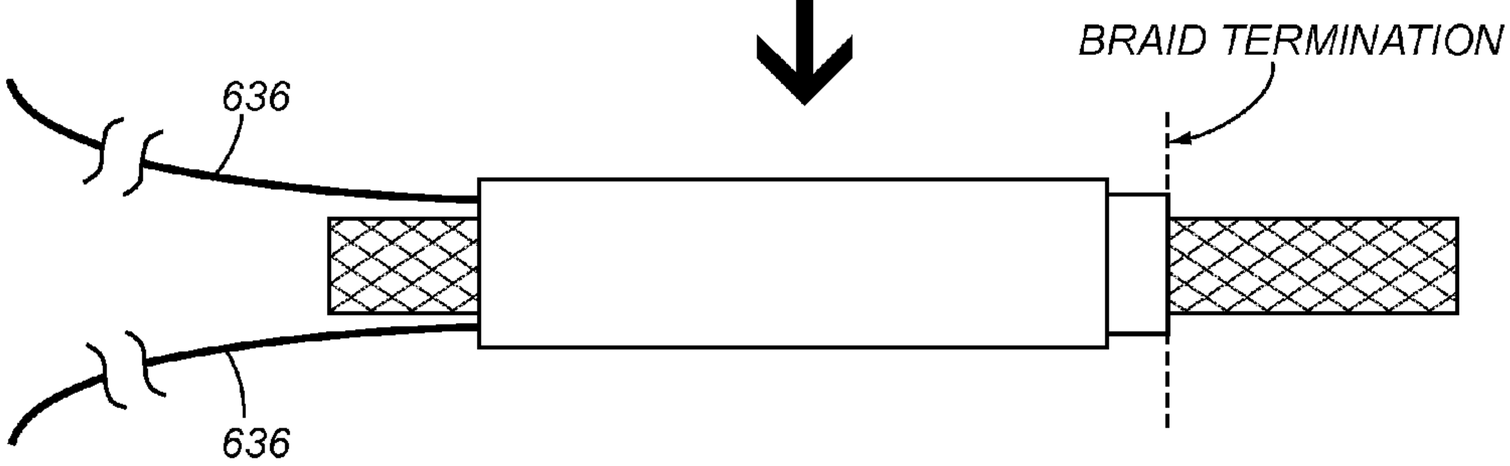


FIG. 11G

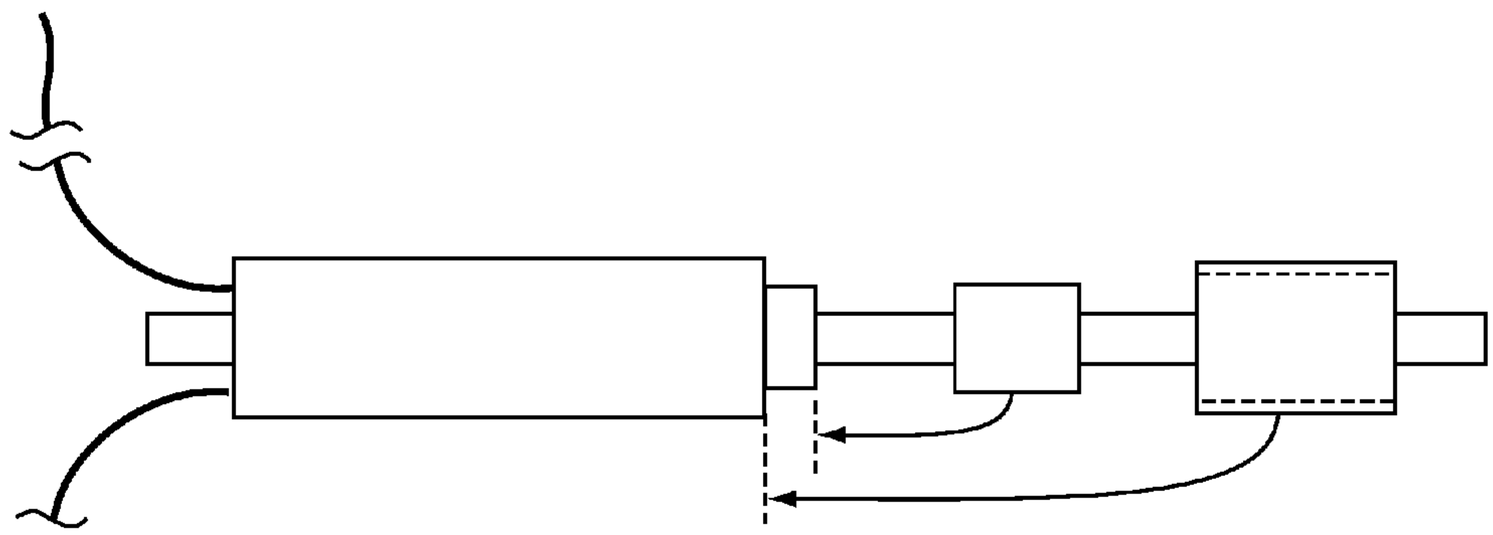

FIG. 11H

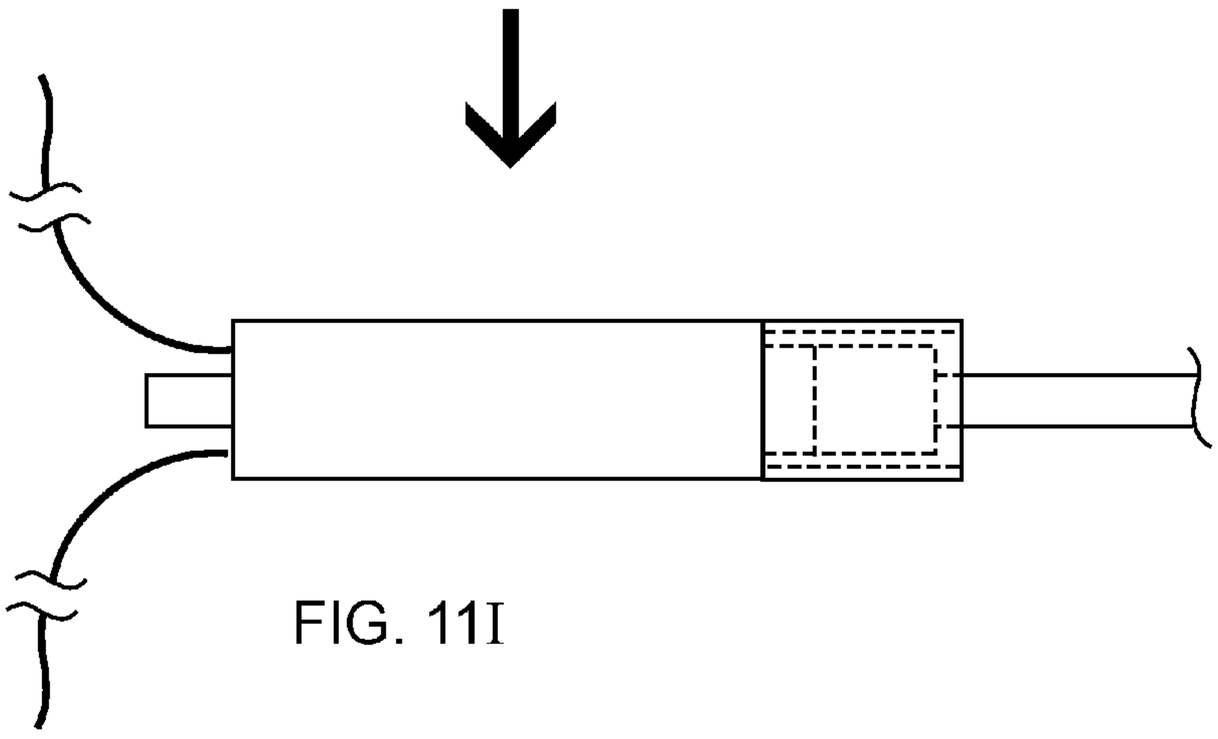

FIG. 11I

*LAMINATE, TRIM, FORM, REMOVE INNER MANDREL*

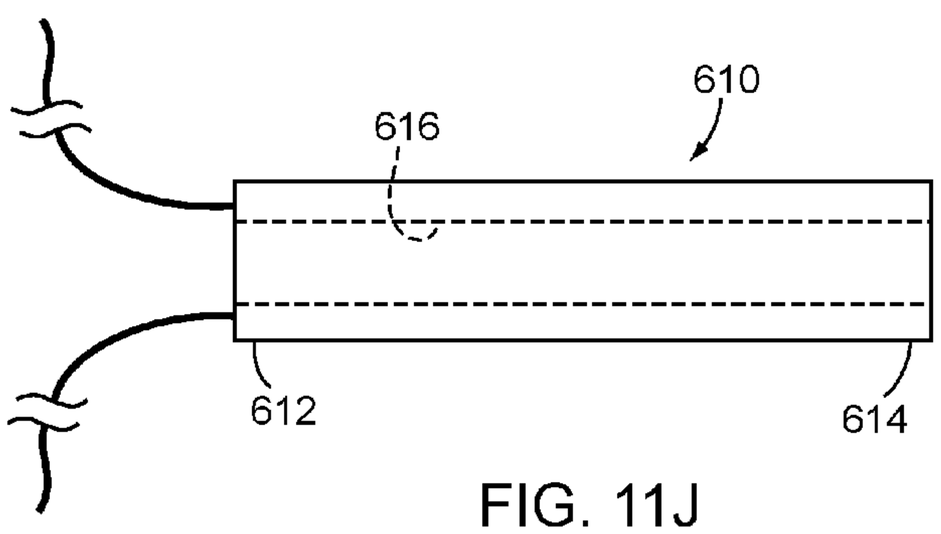


FIG. 11J

# CATHETER DEVICES AND METHODS FOR MAKING THEM

## RELATED APPLICATION DATA

This application is a continuation of co-pending International Application No. PCT/US2015/051284, filed Sep. 21, 2015, which claims benefit of provisional application Ser. No. 62/053,188, filed Sep. 21, 2014, the entire disclosures of which are expressly incorporated by reference herein.

## FIELD OF THE INVENTION

The present invention relates generally to reinforced catheters, sheaths, or other tubular devices including multiple lumens, and, more particularly, to catheters, sheaths, or other tubular devices including braided or other reinforcement configurations and one or more lumens that change position relative to the reinforcement members and/or a central lumen along the length of the tubular devices, and to methods for making such tubular devices.

## BACKGROUND

Elongate tubular devices, such as diagnostic or treatment catheters or sheaths may be provided for introduction into a patient's body, e.g., the patient's vasculature or other body lumens. For example, a catheter may have a distal portion configured to be introduced into a body lumen and advanced to one or more desired locations within the patient's body by manipulating a proximal end of the catheter.

To facilitate introduction of such a catheter, one or more wires, cables, or other steering elements may be provided within the catheter, e.g., that are coupled to the distal portion and may be pulled or advanced from the proximal end to deflect the distal portion. For example, a steering element may be provided that is intended to deflect the distal portion within a predetermined plane and/or into a desired curved shape.

Pull wires are a common way to impart deflection ability to such a catheter. However, there are a number of drawbacks associated with such pull wires. For example, a pull wire occupies a significant amount of space within the catheter body. In addition, a pull wire frequently needs to be reinforced, e.g., on the inside and outside of the braid or other reinforcement of the catheter, e.g., to prevent "pull through" or loosening when the pull wire is actuated by pushing or pulling, i.e., the resulting bending moment may cause the pull wire to separate layers of or tear at least partially through the wall of catheter, potentially splitting the catheter and/or decreasing the mechanical actuation ability of the pull wire. Further, a pull wire can make the torque properties of the catheter non-homogenous, making it difficult or impossible to torque the catheter when the pull wire is actuated, e.g., within a tortuous pathway. Further, auxiliary lumens, in particular those located in the wall of a large bore sheath, are difficult to manufacture with consistency due to difficulties with alignment, hand assembly, and the like.

Accordingly, there is a need for improved catheters, sheaths, and other tubular devices and methods of their manufacture.

## SUMMARY

The present invention is directed to reinforced catheters, sheaths, or other tubular devices including multiple lumens.



More particularly, the present invention is directed to catheters, sheaths, or other tubular devices, e.g., steerable tubular devices, including braided or other reinforcement configurations and one or more lumens that change position relative to the reinforcement members and/or a central lumen along the length of the tubular devices, and/or to methods for making such catheters, sheaths, or other tubular devices.

In accordance with one embodiment, a tubular device is provided, e.g., for a catheter or sheath, comprising a proximal end and a distal end sized for introduction into a patient's body. The tubular device may include a central lumen extending between the proximal and distal ends; an auxiliary lumen extending between the proximal and distal ends adjacent the central lumen; and one or more reinforcement members including windings extending around the central lumen between the proximal and distal ends. In addition, one or more layers may surround the one or more reinforcement members and/or the lumens. At one or more locations along the length of the tubular device, the auxiliary lumen may change position relative to the reinforcement members, e.g., may be at least partially braided, woven, or directed into the reinforcement members, between the reinforcement members and the central lumen, and outside the reinforcement members along different portions of the tubular device.

In accordance with yet another embodiment, a method is provided for making a tubular body that includes directing a primary mandrel along a central axis of a braiding apparatus such that the primary mandrel is surrounded by a plurality of horn gears and/or bobbin carriers or other reinforcement carrying elements; and directing a secondary mandrel adjacent to the primary mandrel and offset from the central axis. One or more reinforcement members from the reinforcement carrying elements may be wrapped around the primary mandrel, and an outer jacket may be applied around the primary and secondary mandrels after wrapping the one or more reinforcement members.

Along a first portion of the primary mandrel, the reinforcement members may be directed such that some windings of the reinforcement members surround the primary mandrel and pass between the primary mandrel and the secondary mandrel, and some windings of the reinforcement members surround both the primary and secondary mandrels. Along a second portion of the primary mandrel, all of the windings of the reinforcement members may surround both the primary mandrel and the secondary mandrel. Optionally, along a third portion of the primary mandrel, the reinforcement members may be wrapped around the primary mandrel such that the secondary mandrel is outside the reinforcement members.

Alternatively, along a first portion of the primary mandrel, all of the windings of the reinforcement members may surround both the primary mandrel and the secondary mandrel, and along a second portion, the reinforcement members may be directed such that some windings of the reinforcement members surround the primary mandrel and pass between the primary mandrel and the secondary mandrel, and some windings of the reinforcement members surround both the primary and secondary mandrels. Optionally, along a third portion of the primary mandrel, the reinforcement members may be wrapped around the primary mandrel such that the secondary mandrel is outside the reinforcement members.

In another alternative, along a first portion of the primary mandrel, the reinforcement members may be wrapped around the primary mandrel such that the secondary mandrel is outside the reinforcement members, and along a second

portion of the primary mandrel, all of the windings of the reinforcement members may surround both the primary mandrel and the secondary mandrel or the reinforcement members may be wrapped around the primary mandrel such that the secondary mandrel is outside the reinforcement members

The primary mandrel may be removed to define a primary lumen within the tubular body. In addition, the method may also include removing the secondary mandrel to define an auxiliary lumen within the tubular body adjacent the primary lumen. As a result, the position of the auxiliary lumen, e.g., radially and/or circumferentially relative to the primary lumen, may change along the length of the tubular body, e.g., between the first, second, and/or optionally third portions.

In accordance with another embodiment, a method is provided for making a tubular body that includes directing a primary mandrel along a central axis of a braiding apparatus such that the primary mandrel is surrounded by a plurality of reinforcement carrying elements; providing a plurality of reinforcement carrying elements in a predetermined configuration relative to the central axis; providing a source of a secondary mandrel at a first location adjacent to the primary mandrel and offset from the central axis; with the secondary mandrel feeding from the source at the first location, wrapping reinforcement members from the reinforcement carrying elements helically around a first portion of the primary mandrel such that some windings of the one or more reinforcement members surround the primary mandrel and pass between the primary mandrel and the secondary mandrel and some windings of the one or more reinforcement members surround both the primary and secondary mandrels; moving the source of secondary mandrel to a second location; with the secondary mandrel feeding from the source at the second location, wrapping reinforcement members from the reinforcement carrying elements helically around a second portion of the primary mandrel such that either a) all of the reinforcement members also surround the secondary mandrel; or b) the second secondary mandrel remains outside the reinforcement members. An outer jacket may be applied around the primary and secondary mandrels after wrapping the one or more reinforcement members therearound; and the primary mandrel may be removed to define a primary lumen within the tubular body.

In accordance with still another embodiment, a method is provided for making a tubular body using a braiding apparatus comprising a primary mandrel source configured to direct a primary mandrel along a central axis, a plurality of horn gears rotatably mounted around the central axis in a predetermined arrangement such that the horn gears rotate about respective horn gear axes and carriers travel along a generally circular path around the central axis during operation of the braiding apparatus, and a secondary mandrel source configured to direct a secondary mandrel towards the primary mandrel from one of a plurality of locations comprising a first location disposed adjacent the central axis within the generally circular path, a second location aligned with a horn axis of one of the horn gears, and a third location outside the generally circular path. The method may include braiding a first portion of the primary mandrel by: a) directing the primary mandrel along the central axis; b) directing the secondary mandrel from one of the plurality of locations towards the primary mandrel such that the secondary mandrel is disposed adjacent the first portion of the mandrel; and c) wrapping reinforcement members from the carriers around the first portion of the primary mandrel. The method may also include braiding a second portion of the primary mandrel by: a) moving the secondary mandrel source another of the plurality of locations; b) directing the primary mandrel further along the central axis; and c) wrapping reinforcement members from the carriers around the second portion of the primary mandrel. An outer jacket may be applied around the first and second portions of the primary mandrel and the secondary mandrel, and the primary mandrel may be removed to define a primary lumen within the tubular body.

In accordance with yet another embodiment, a tubular device is provided for a catheter or sheath comprising a proximal end and a distal end sized for introduction into a patient's body that includes a central lumen extending between the proximal and distal ends; an auxiliary lumen extending at least partially between the proximal and distal ends adjacent the central lumen; one or more reinforcement members comprising windings extending helically around the central lumen between the proximal and distal ends; and one or more layers surrounding the one or more reinforcement members, wherein the tubular device comprises a first portion in which at least some of the windings pass between the central and auxiliary lumens and at least some of the windings surround both the central and auxiliary lumens, and a second portion in which either a) all of the windings surround both the central and auxiliary lumens or b) all of the windings surround the central lumen and the auxiliary lumen is disposed outside the windings.

In accordance with still another embodiment, an apparatus is provided for performing a procedure within a patient's body that includes a tubular member comprising a proximal end, a distal end sized for introduction into a patient's body, a central axis extending therebetween, and a distal portion extending distally from an intermediate portion to the distal end; a primary lumen extending between the proximal and distal ends and surrounding at least a portion of the central axis; a steering element lumen extending at least partially between the proximal and distal ends adjacent the primary lumen; a steering element slidably disposed within the steering element lumen and comprising a distal end fixed to the tubular member distal end and a proximal end adjacent the proximal end of the tubular member; and an actuator on the proximal end coupled to the steering element proximal end such that, actuation of the actuator applies axial tension or compression to the steering element, thereby causing the distal portion to bend. One or more reinforcement members comprising windings may extend around the primary lumen between the proximal and distal ends, and one or more layers may surround the one or more reinforcement members, wherein the tubular member comprises a first portion in which at least some of the windings pass between the primary lumen and the steering element lumen and at least some of the windings surrounding both the primary lumen and the steering element lumen, and a second portion in which either a) all of the windings surround both the primary lumen and the steering element lumen or b) all of the windings surround the primary lumen and the steering element lumen is disposed outside the windings.

Other aspects and features of the present invention will become apparent from consideration of the following description taken in conjunction with the accompanying drawings.

## BRIEF DESCRIPTION OF THE DRAWINGS

The drawings illustrate exemplary embodiments of the invention, in which:

FIG. **1**A is a perspective view of an exemplary embodiment of a catheter, including multiple lumens extending between proximal and distal ends thereof, and including a steerable distal portion.

FIG. **1**B is a cross-sectional side view of the catheter of FIG. **1**A, taken along line **1**B-**1**B, showing reinforcement members positioned around primary and auxiliary lumens of the catheter.

FIG. **2** is a side view of a first example of a catheter including a primary lumen and an auxiliary lumen that changes position along the length of the catheter.

FIGS. **2**A-**2**D are cross-sectional views of the catheter of FIG. **2** taken at different locations along the length of the catheter.

FIG. **3** is a side view of a second example of a catheter including a primary lumen and an auxiliary lumen that changes position along the length of the catheter.

FIGS. **3**A-**3**D are cross-sectional views of the catheter of FIG. **2** taken at different locations along the length of the catheter.

FIG. **4**A is a schematic of an exemplary embodiment of a braiding apparatus for making a reinforced tubular member including multiple mandrels supported by reinforcement members.

FIG. **4**B is a front view of an arrangement of horn gears for creating a braided configuration of reinforcement members that may be included in the braiding apparatus of FIG. **4**A and including various locations for sources of mandrels.

FIG. **4**C is a cross-sectional view of a catheter showing the locations of mandrels corresponding to the different locations for the sources of mandrels shown in FIG. **4**B.

FIG. **5** is a partial cross-sectional side view of an exemplary embodiment of a catheter including a steering lumen for receiving a steering element.

FIG. **6** is a partial cross-sectional side view of another embodiment of a catheter including a plurality of electrodes mounted thereon and including a lumen for receiving one or more conductors for coupling to the electrodes.

FIG. **7**A is a side view of a portion of a catheter subassembly including a primary mandrel and a secondary mandrel wrapped by reinforcement members and including a section of the secondary mandrel that has been pulled outside the reinforcement members.

FIG. **7**B is a side view of a portion of a catheter resulting from the catheter subassembly of FIG. **7**A that includes a discontinuous auxiliary lumen that communicates with side openings in the wall of the catheter.

FIG. **8**A is a side view of a portion of another embodiment of a catheter including an auxiliary lumen that has a variable diameter.

FIG. **8**B is a side view of a portion of a steering element that may be received in the auxiliary lumen of the catheter of FIG. **8**A.

FIG. **9** is a side view of a portion of still another embodiment of a catheter including one or more stiffening elements embedded into a wall of the catheter.

FIG. **9**A is a cross-section of the catheter of FIG. **9** taken across **9**A-**9**A.

FIG. **10** is a side view of a mandrel/reinforcement subassembly including a pair of secondary mandrels partially braided into a length of the subassembly.

FIGS. **10**A-**10**C are cross-sectional views of the subassembly of FIG. **10** taken along sections **10**A-**10**A, **10**B-**10**B, and **10**C-**10**C, respectively.

FIGS. **11**A-**11**J show an exemplary method for making a steerable catheter including a lapped braid with a pull wire ring.



## DETAILED DESCRIPTION OF THE EXEMPLARY EMBODIMENTS

Turning to the drawings, FIGS. **1**A and **1**B show an exemplary embodiment of an apparatus **10** for introduction into a body lumen (not shown), e.g., for performing a diagnostic and/or therapeutic procedure within a patient's body. In exemplary embodiments, the apparatus **10** may be a guide catheter, a sheath, a procedure catheter, e.g., an imaging catheter, an ablation and/or mapping catheter, a balloon catheter, or other tubular device sized for introduction into a body lumen, such as a vessel within a patient's vasculature, a passage within a patient's gastrointestinal tract, urogenital tract, reproductive tract, respiratory tract, lymphatic system, and the like (not shown). In exemplary embodiments, the apparatus **10** may have a length between about ten and one hundred thirty centimeters (10-130 cm), and an outer diameter between about four and twenty-four French (4-24 Fr or 1.33-8.0 mm).

Generally, the apparatus **10** is an elongate tubular member including a proximal end **12**, a distal end **14** sized for insertion into a body lumen, a central longitudinal axis **16** extending between the proximal and distal ends **12**, **14**, and one or more lumens **18** extending between the proximal and distal ends **12**, **14**. For example, as shown in FIG. **1**B, the apparatus **10** may include a central or primary lumen **18***a*, e.g., sized for receiving or carrying one or more instruments or other elements (not shown). In exemplary embodiments, the central lumen **18***a* may be sized for receiving or carrying a guide wire, procedure catheter, balloon catheter, ablation catheter, cardiac lead, needle, or other instrument (not shown), one or more wires or other conductors, one or more optical fibers, one or more tubes or accessory lumens, one or more mechanical elements, one or more sensors, and/or sized for delivering and/or removing fluids or other flowable agents or materials therethrough.

In one embodiment, shown in FIG. **1**A, the central lumen **18***a* may exit at or communicate with an outlet **17** in the distal end **14**, e.g., to allow a guidewire or other instrument (not shown) to pass therethrough and/or for delivering or aspirating fluid therethrough. Alternatively, the central lumen **18***a* may be enclosed, e.g., terminating within or adjacent the distal end, e.g., by an electrode, cap, or other component (not shown) to isolate the central lumen **18***a* and/or elements carried therein from the environment outside the apparatus **10**.

Returning to FIG. **1**B, in addition to the central lumen **18***a*, the apparatus **10** includes an auxiliary lumen **18***b*, e.g., extending adjacent the central lumen **18***a*, e.g., substantially parallel to and radially offset relative to the central axis **16**. For example, in FIG. **5**, an exemplary embodiment of a catheter **110** is shown in which the auxiliary lumen **118***b* may be a steering element lumen configured to receive a pull wire or other steering element **136** therein, e.g., to bend or otherwise deflect a distal portion of the catheter **110**, as described further below. In FIG. **6**, an exemplary embodiment of a catheter **210** is shown in which the auxiliary lumen **218***b* may receive one or more wires or conductors **236** for coupling to one or more electrodes **238** mounted on the distal portion of the catheter **210**, also as described further below.

With continued reference to FIGS. **1**A and **1**B, optionally, the apparatus **10** may include one or more additional lumens (not shown), e.g., one or more additional steering element lumens, conductor lumens, inflation lumens (e.g., if the apparatus **10** includes one or more balloons, not shown on the distal end **14**), and/or accessory lumens. For example, a

pair of auxiliary lumens may be provided (not shown) on opposite sides of the apparatus **10**, e.g., offset about one hundred eight degrees (180°) around the circumference of the apparatus **10**.

Optionally, the auxiliary lumen(s) may have a variety of cross-sectional shapes and/or sizes, e.g., a substantially circular shape, an elliptical or oval shape, a substantially rectangular shape, a triangular shape, a pair of overlapping circles shape, and the like, e.g., similar to the devices disclosed in U.S. Publication No. 2014/0323964, the entire disclosure of which is expressly incorporated by reference herein. The shape and/or size of the auxiliary lumen(s) may be substantially uniform along the length of the apparatus **10** or may vary at different locations, as described elsewhere herein.

The auxiliary lumen **18***b* is generally radially offset from the central axis **16** substantially along the length of the apparatus **10**, e.g., entirely from the distal end **14** to the proximal end **12**. In addition, the radial and/or circumferential position of the auxiliary lumen **18***b* may change relative to the primary lumen **18***a* and/or other components of the apparatus **10** at various locations along the length of the apparatus **10**, as described elsewhere herein.

Returning to FIG. **1**A, the distal end **14** may include a tapered, rounded, or otherwise shaped distal tip **15**, e.g., to provide a substantially atraumatic tip and/or to facilitate advancement or navigation through various anatomy. In addition or alternatively, the distal end **14** may include one or more therapeutic and/or diagnostic elements, e.g., one or more balloons, stents, sensors, electrodes, ablation elements, thermocouples, steering mechanisms, imaging devices, helical anchors, needles, and the like (not shown), depending upon the particular intended application for the apparatus **10**. Further, in addition or alternatively, the distal end **14** may include one or more markers or other features to enhance radiopacity and/or visibility under ultrasound, MRI or other imaging modalities, e.g., by mounting one or more platinum elements on the distal end **14**, doping one or more regions of the distal end **14** with tungsten or barium sulfate, and/or other methods known in the art.

Optionally, as shown in FIG. **1**A, the proximal end **12** may include a handle or hub **30**, e.g., configured and/or sized for holding and/or manipulating the apparatus **10** from the proximal end **12**. In addition, the handle **30** may include one or more ports, e.g., port **32***a* communicating with the central lumen **18***a*, or other respective lumens (not shown). Optionally, the port **32***a* may include one or more valves, e.g., a hemostatic valve (also not shown), which may provide a substantially fluid-tight seal, while accommodating insertion of one or more instruments or fluids into the central lumen **18***a*. Optionally, a side port (not shown) may be provided on the handle **30**, e.g., for delivering fluid into and/or aspirating fluid from the primary lumen **18***a*, e.g., around an instrument inserted into the primary lumen **18***a*. Optionally, the handle **30** and/or proximal end **12** may include one or more connectors, such as luer lock connectors, electrical connectors, and the like, for connecting other devices (not shown) to the apparatus **10**, such as syringes, displays, controllers, and the like (also not shown).

In addition, the handle **30** may include one or more actuators, such as sliders, buttons, switches, rotational actuators, and the like, e.g., for activating and/or manipulating components (also not shown) on the distal end **14** or otherwise operating the apparatus **10**. For example, as shown in FIG. **1**A, an actuator **34** may be provided that is coupled to a proximal end of a steering element (not shown) within the auxiliary lumen **18***b*, e.g., similar to the embodiment shown in FIG. **5**, as described further elsewhere herein.

Generally, with particular reference to FIG. **1**B, the apparatus **10** may include an inner liner **40**, e.g., at least partially or entirely surrounding or otherwise defining the central lumen **18***a*, a reinforcement layer **42** surrounding the inner liner **40**, and an outer jacket **44** surrounding and/or encasing the reinforcement layer **42**, each of which may extend at least partially between the proximal and distal ends **12**, **14** of the apparatus **10**. The reinforcement layer **42** and/or outer jacket **44** may be attached to the inner liner **40**, e.g., by laminating, adhering, adhesive bonding, ultrasonic welding, reflowing or other heating, and the like, as described elsewhere herein.

In an exemplary embodiment, the central lumen **18***a* is defined by an inner liner **40***a* including an inner surface **41***a*. The inner liner **40***a* may be formed from lubricious material, e.g., PTFE, to provide a lubricious inner surface **41***a*. Alternatively, the inner liner **40** may be formed from one or more layers of thermoplastic or other polymeric material including one or more coatings on the inner surface **41***a* having desired properties, e.g., a hydrophilic and/or lubricious coating, e.g., similar to the liners disclosed in U.S. Pat. Nos. 7,550,053 and 7,553,387, and U.S. Publication No. 2009/0126862, the disclosures of which are expressly incorporated by reference herein.

Optionally, as shown in FIG. **1**B, an inner liner **40***b* may also at least partially surround the auxiliary lumen **18***b*, which may be formed from a lubricious material and/or may include one or more coatings on its inner surface **41***b*, similar to the inner liner **40***a*. The inner surface **41***b* of the auxiliary lumen **18***b* may have a substantially uniform cross-section, as shown in FIG. **1**B. Alternatively, the inner surface **41***b* of the auxiliary lumen **18***b* may have a textured or other variable cross-section along, e.g., along its length and/or about its circumference (not shown).

Optionally, any or all of the inner liner **40***a*, reinforcement layer **42**, and/or outer jacket **44** may be formed from multiple layers of like or different materials (not shown), e.g., to provide desired material properties in the different portions of the apparatus **10**. In an exemplary embodiment, the outer jacket **44** may be formed from PEBAX, nylon, urethane, and/or other thermoplastic material, e.g., such that the material of the outer jacket **44** may be heated and reflowed and/or otherwise formed around the components defining the lumens **18**, e.g., as described elsewhere herein.

In one embodiment, one or more of the layers of the apparatus **10** may have a substantially homogenous construction between the proximal and distal ends **12**, **14**. Alternatively, the construction may vary along the length of the apparatus **10** to provide desired properties, e.g., between proximal, intermediate, and distal portions **20**, **22**, **24**. For example, a proximal portion **20** of the apparatus **10** adjacent the proximal end **12** may be substantially rigid or semi-rigid, e.g., providing sufficient column strength to allow the distal end **14** of the apparatus **10** to be pushed or otherwise manipulated from the proximal end **12**, while the distal portion **24** may be substantially flexible. As described further below, the distal portion **24** of the apparatus **10** may be steerable, i.e., may be bent, curved, or otherwise deflected substantially within a steering plane, as described further below.

Returning to FIG. **1**B, the reinforcement layer **42** may include one or more reinforcing members, e.g., wound in a braided or other helical configuration around the inner liner **40***a*, e.g., using a braiding apparatus such as that shown in FIGS. **4**A and **4**B, and the outer jacket **44** may include one

or more tubular layers surrounding the reinforcement layer **42** and/or between the reinforcement layer **42** and the inner liner **40***a*. In an exemplary embodiment, the reinforcement layer **42** may include one or more, or a plurality of, round or flat (e.g., rectangular, elliptical, or flat oval) wires, filaments, strands, or other reinforcement members **43**, e.g., formed from metal, such as stainless steel, plastic, such as PEEK, glass, woven or twisted fibers, such as aramid, and the like, or composite materials.

In one embodiment, a plurality of reinforcement members **43** may be braided around the inner liner **40***a*, e.g., with each reinforcement member **43** having the same material and/or shape. Alternatively, the reinforcement members **43** may have different sizes and/or shapes, e.g., a first size or shape extending helically in a first direction and a second size or shape (different than the first) extending helically in a second direction (e.g., opposite the first direction).

The reinforcement layer **42** may be configured to substantially transfer torsional forces between the proximal and distal ends **12**, **14**, e.g., to allow the apparatus **10** to be twisted from the proximal end **12** to rotate the distal end **14** about the longitudinal axis **16** within a patient's body. In addition, the reinforcement layer **42** may allow the distal end **14** of the apparatus **10** to be advanced or otherwise manipulated within a patient's body from the proximal end **12** without substantial risk of buckling and/or kinking. The pitch of the reinforcement layer **42** may be varied along the length of the apparatus **10**, e.g., in order to optimize mechanical properties of various segments or portions of the apparatus **10**.

In addition, the location of the reinforcement layer **42** may vary relative to the central lumen **18***a* and/or auxiliary lumen **18***b*, e.g., as the auxiliary lumen **18***b* transitions to different radial locations within the wall of the apparatus **10**. For example, FIG. **2** shows an example of a catheter **10**A that includes a central lumen **18**A-a that extends substantially along a central axis **16**A and is surrounded by a reinforcement layer **42**, which may be similar to any of the embodiments described elsewhere herein. In addition, the catheter **10**A includes an auxiliary lumen **18**A-b that extends between proximal and distal ends **12**A, **14**A of the catheter **10**A adjacent the central lumen **18**A-a at different radial and/or circumferential locations. As shown in FIG. **2**A, along a proximal portion, the auxiliary lumen **18**A-b may be braided into the reinforcement layer **42**, while, as shown in FIG. **2**B, at an intermediate portion, the auxiliary lumen **18**A-b may transition outside the reinforcement layer **42**. Further, as shown in FIG. **2**C, the auxiliary lumen **18**A-b may transition to a location closer to the central lumen **18**A-a such that the reinforcement layer **42** surrounds both lumens **18**A-a, **18**A-b. Finally, as shown in FIG. **2**D, the auxiliary lumen **18**A-b may transition again and be braided into the reinforcement layer **42** along a distal portion to the distal end **14**A.

With continued reference to FIGS. **2** and **2**A-D, in an exemplary embodiment, a deflectable catheter shaft may be constructed wherein one or more auxiliary lumens **18**A-b (e.g., a single auxiliary lumen or two auxiliary lumens spaced approximately one hundred eighty degrees (180°) apart) may be braided into or within the reinforcement layer **42** as shown in FIG. **2**D at an intermediate portion (e.g., corresponding to FIG. **2** sections B and/or C) while the auxiliary lumen **18**A-b may transition outside the reinforcement layer **42** as shown in FIG. **2**B at a distal and proximal location (e.g., corresponding to FIG. **2** sections A and D). Additionally, the auxiliary lumen(s) **18**A-b may pass through a jacket layer (as described elsewhere herein) overlying the reinforcement layer at or near the point(s) of transition from within to outside of the reinforcement layer **42**.

In a further exemplary embodiment, the auxiliary lumen(s) **18**A-b may pass through a jacket layer at or near the proximal transition(s) from within to outside the reinforcement layer and may terminate under or within the jacket layer at or near the distal transition(s) from within to outside the reinforcement layer, e.g., such that an actuator wire ring (not shown) with actuator wire(s) (not shown) attached may be positioned adjacent the distal point(s) of transition with actuator wire(s) travelling through the auxiliary lumen(s) **18**A-b over the intermediate portion, the actuator wire ring being positioned under the jacket adjacent the distal transition and the actuator wire(s) exiting the a wall of the shaft through the jacket adjacent the proximal transition(s). A handle, such as that shown in FIG. **1**, may be positioned around the proximal exit(s) that includes one or more actuators attached or otherwise coupled to the actuator wires at this position.

With continued reference to FIGS. **2** and **2**A-D, in another exemplary embodiment, a deflectable catheter shaft may be constructed wherein one or more auxiliary lumens **18**A-b (e.g., a single auxiliary lumen or two auxiliary lumens spaced approximately one hundred eighty degrees (180°) apart) may be braided under the reinforcement layer **42** as shown in FIG. **2**C at an intermediate portion (e.g., corresponding to FIG. **2** sections B and/or C) while the auxiliary lumen **18**A-b may transition outside the reinforcement layer **42** as shown in FIG. **2**B at a distal and proximal location (e.g., corresponding to FIG. **2** sections A and D). Additionally, the auxiliary lumen(s) **18**A-b may pass through a jacket layer (as described elsewhere herein) overlying the reinforcement layer at or near the point(s) of transition from under to outside of the reinforcement layer **42**.

In a further embodiment, the auxiliary lumen(s) **18**A-b may pass through a jacket layer at or near the proximal transition(s) from under to outside the reinforcement layer and may terminate under or under the jacket layer at or near the distal transition(s) from under to outside the reinforcement layer, e.g., such that an actuator wire ring (not shown) with actuator wire(s) (not shown) attached may be positioned adjacent the distal point(s) of transition with actuator wire(s) travelling through the auxiliary lumen(s) **18**A-b over the intermediate portion, the actuator wire ring being positioned under the jacket adjacent the distal transition and the actuator wire(s) exiting the a wall of the shaft through the jacket adjacent the proximal transition(s). A handle, such as that shown in FIG. **1**, may be positioned around the proximal exit(s) and one or more actuators may be attached or otherwise coupled to the actuator wires at this position.

FIG. **3** shows another example of catheter **10**B, similar to that shown in FIG. **2** except that the auxiliary lumen **18**B-b may extend along a proximal portion close to the central lumen **18**B-a surrounded by the reinforcement layer **42** (as shown in FIG. **3**A), may then transition and extend along an intermediate portion outside the reinforcement layer **42** (as shown in FIG. **3**B), may again transition to a location surrounded by the reinforcement layer **42** (as shown in FIG. **3**C), and finally may transition to a location outside the reinforcement layer **42** along a distal portion (as shown in FIG. **3**D).

Thus, again with general reference to FIGS. **1**A and **1**B, in any of the apparatus and methods herein, it will be appreciated that the location of the auxiliary lumen **18***b* and/or reinforcement members **43** of the reinforcement layer **42** may be changed along the length of the apparatus **10** to

provide desired mechanical and/or other performance characteristics for the final apparatus.

For example, with reference to FIG. **5**, an apparatus **110** is shown in which a distal portion **124** of the apparatus **10** is steerable, e.g., using one or more pull wires, cables, fibers, threads, filaments, or other steering elements, such as a pull wire **136** slidably received within auxiliary lumen **118***b*. The steering element **136** generally includes a proximal end (not shown) coupled to an actuator, e.g., such as the actuator **34** on the handle **30** shown in FIG. **1**, and extends from a proximal portion (not shown) through an intermediate portion **122** and into the distal portion **124**. A distal end **136***b* of the steering element **136** may be fixed or otherwise coupled to the distal end **114**, e.g., to a component defining or adjacent the distal tip (not shown).

The steering element **136** may be formed from materials capable of substantially transferring any axial forces applied at the proximal end to the distal end **114**, as is known in the art. Optionally, the steering element **136** may include a coating, e.g., PTFE, parylene, silicone, or other lubricious material, an outer sleeve, e.g., formed from HDPE, PTFE, and the like, to reduce friction between the steering element and the wall of the auxiliary lumen **18***b*. Alternatively or in addition, the inner surface of the auxiliary lumen **118***b* may be formed from lubricious material and/or may include one or more coatings, as described elsewhere herein. Alternatively or in addition, the auxiliary lumen **18***b* may include one or more incompressible elements, e.g., a tightly wound coil therearound, e.g., to prevent compression, which may otherwise lead to creating a bending moment along at least part of its length.

During use, the actuator may be activated, e.g., directed proximally or distally relative to the handle and/or the proximal end (not shown), to apply an axial force to the steering element **136**, e.g., tension (when the steering element is pulled) or compression (when the steering element is advanced). Because the steering element **136** is slidable within the auxiliary lumen **118***b*, the axial force is translated and applied to the distal end **136***b* coupled to the distal end **114**. Further, because the auxiliary lumen **118***b* is offset from the central axis **116** along at least the distal portion **124**, the axial force applies a bending moment, thereby causing the distal portion **124** to curve or otherwise bend in a desired plane or other manner. Optionally, the proximal and intermediate portions **122** of the apparatus **110** may be constructed to prevent or minimize bending forces caused by actuation of the steering element **136**.

In the configuration shown in FIG. **5**, along the distal portion **124**, a second segment **118***b*-**2** of the auxiliary lumen **118***b* may be surrounded by the reinforcement layer **142**, e.g., immediately adjacent the central lumen **118***a* (e.g., similar to the location shown in FIG. **3**A), and then may transition such that a first segment **118***b*-**1** of the auxiliary lumen **118***b* is outside the reinforcement layer **142**, e.g., closer to an outer surface of the apparatus **110** along at least the intermediate portion **122** (and/or optionally along the proximal portion to the proximal end and/or handle, not shown). Alternatively, the second segment **118***b*-**2** may be braided into the reinforcement layer **142** (e.g., similar to the location shown in FIG. **2**A).

Locating the second segment **118***b*-**2** surrounded by the reinforcement layer **142** may enhance performance properties of the steering element **136** and/or may reduce the risk of the steering element **136** tearing through the wall of the distal portion **124**, e.g., when a proximal force or tension is applied to the steering element **136**. Locating the first segment **118***b*-**1** outside the reinforcement layer **142** may facilitate accessing the auxiliary lumen **118***b*, e.g., during manufacturing and/or assembly, to couple the proximal end of the steering element **136** to an actuator and/or other components (not shown) at the proximal end of the apparatus **110**.

Conversely, if the apparatus **110** were intended to include one or more sensors, actuators, electrodes, imaging element, or other components on the distal portion, the configuration could be reversed. For example, the location of the second segment **118***b*-**2** of the auxiliary lumen **118***b* may extend from a proximal end of the apparatus **110** to a distal portion and then may transition to the location of the first segment **118***b*-**1**, e.g., outside the reinforcement layer **142** along the distal portion. This configuration may facilitate accessing the auxiliary lumen **118***b* at the distal portion, e.g., to couple one or more wires or conductors disposed within the second segment **118***b*-**2** of the auxiliary lumen **118***b* to the sensors, actuators, electrodes, imaging elements, and/or or other components, e.g., since the auxiliary lumen **118***b* is closer to the outer surface of the apparatus **10**. Along the proximal and/or intermediate portions, the auxiliary lumen **118***b* and consequently the conductor(s) may be disposed deeper within the apparatus **110**, e.g., beneath and/or within the reinforcement layer **142**, which may at least partially shield or otherwise protect the conductor(s).

Turning to FIG. **6**, in another embodiment, an apparatus **210** may be provided that includes a plurality of sensors, actuators, electrodes, imaging elements, and/or or other components **238** on a distal portion **224** of the catheter **210**, which may be coupled to one or more wires or conductors **236** extending through an auxiliary lumen **218***b* proximally from the distal portion **224**, e.g., to one or more connectors and/or electronics at the proximal end (not shown) of the apparatus **210**.

In the exemplary embodiment shown, the auxiliary lumen **218***b* may extend generally along the distal portion **224** braided into the reinforcement layer (e.g., similar to the location shown in FIG. **2**A) or completely surrounded by the reinforcement layer (e.g., similar to the location shown in FIG. **3**A) as represented by segments **218***b*-**1**, but may transition to segments **218***b*-**2** that are positioned outside the reinforcement layer (e.g., similar to the location shown in FIG. **3**B) for a relatively short distance, e.g., under the locations intended for the electrodes **238**. With the auxiliary lumen **218***b* closer to the outer surface at the short segments **218***b*-**2**, any wires or conductors within the auxiliary lumen **218***b* may be easily accessed during manufacturing or assembly, e.g., to expose and couple the electrodes **238** to the conductor(s) when the electrodes **238** are mounted to the distal portion **224**. Otherwise, the conductor(s) may be located relatively deep within the apparatus **210**.

Alternatively, the lumen configuration shown in FIG. **6** may be adapted to provide a series of side ports in the distal portion **224** in fluid communication with a proximal portion of the catheter (not shown) by way of an unoccupied auxiliary lumen **218***b*, e.g., such that fluid may delivered through the auxiliary lumen **218***b* and out the side ports and/or aspirated into the auxiliary lumen **218***b* through the side ports from a location outside the distal portion **224**.

In yet another embodiment, shown in FIGS. **7**A and **7**B, an apparatus **310** may be provided that includes a discontinuous auxiliary lumen **318***b* adjacent a central lumen **318***a*. For example, as shown in FIG. **7**B, a first segment **318***b*-**1** of the auxiliary lumen **318***b* may extend proximally from a predetermined location, e.g., to a proximal portion of the apparatus **310** and a second segment **318***b*-**2** may extend distally from the predetermined location such that both

segments communicate with side openings **319** disposed adjacent one another. The auxiliary lumen **318***b* may be braided into a reinforcement layer **342**, e.g., as shown in FIG. **7**A, or disposed at other positions relative to the central lumen **318***a*, as described elsewhere herein.

Turning to FIGS. **4**A-**4**C, various methods may be used for manufacturing and/or assembling any of the embodiments described herein. For example, FIG. **4**A shows an exemplary embodiment of an apparatus **50** for making one or more tubular bodies, such as catheters and/or components for catheters, sheaths, or other tubular devices **8**. Generally, the apparatus **50** includes a plurality of sources **52**, **54** of mandrels **2** and/or liners **4**, a guide **60**, a source **70** of reinforcement members **6**, a drive mechanism **80**, and, optionally, a source **90** of jacket material **7**.

While mandrels, liners, and/or jackets may be provided in discrete segments (not shown), the apparatus **50** may allow for substantially continuous fabrication of tubular bodies, e.g., wrapping a liner material **4***a* around a primary mandrel **2***a* (or the primary mandrel **2***a* may include a tubular or other liner material provided around it on the source **52**, e.g., similar to the liners disclosed in the references incorporated by reference elsewhere herein), positioning an auxiliary mandrel **2***b* (with optional liner material, not shown) adjacent the primary mandrel **2***a*, braiding a plurality of reinforcement members **4** around the mandrels **2**, and optionally, applying outer jacket material **7** around the reinforced mandrels, as described further below.

As used herein, "substantially continuous" means that the apparatus **50** and/or method may operate indefinitely, i.e., to make as few as one or as many as hundreds or thousands of tubular bodies **8**, e.g., by substantially simultaneously feeding components of the tubular bodies **8** from sources **52**, such as reels, through components of the apparatus **50** until the sources **52** are depleted, whereupon new source(s) may be loaded onto the apparatus **50** and the process continued. Alternatively, the apparatus **50** may be used to create discrete lengths of tubular devices, e.g., if the mandrels and/or liners are provided in specific lengths corresponding to one or more individual tubular devices (not shown). In a further alternative, some of the operations may be performed substantially continuously, while other operations are performed on components intended for one or more individual tubular devices.

Thus, the apparatus **50** and methods herein may be used to make one or more relatively long tubular bodies **8**, e.g., that are substantially longer than finished catheters or other tubular devices. For example, one resulting tubular body **8** may be collected, e.g., on a take-up reel or container (not shown), or may be separated into individual shorter tubular bodies, e.g., using a cutter or other tool (not shown), that may be incorporated into individual catheters or other tubular devices, e.g., as described elsewhere herein and/or as disclosed in U.S. Publication No. 2009/0126862, the entire disclosure of which is expressly incorporated by reference herein.

With particular reference to FIG. **4**A, the apparatus **50** may include one or more sources **52** of mandrels **2** and, optionally, one or more sources **54** of liner material **4**, which may be fed into a guide **60** to define lumens of the tubular bodies **8**. For example, a first reel **52***a* may include an elongate primary mandrel **2***a*, e.g., shaped and/or configured to define a primary or central lumen (not shown) of the tubular bodies **8**. Similarly, a second reel **52***b* may include an elongate auxiliary mandrel **2***b*, e.g., shaped and/or configured to define a secondary or auxiliary lumen (also not shown) of the tubular bodies **8**. As described further below, the second reel **52***b* or other source of auxiliary mandrel may be located at one of a plurality of available locations during operation to configure the tubular bodies **8** in a desired manner. Optionally, if additional lumens are desired for the tubular bodies **8**, one or more additional auxiliary mandrels may be provided (not shown), which may also be moved to one or more locations.

The mandrels **2** may have desired cross-sectional shapes and/or sizes corresponding to the desired cross-sections of the lumens, e.g., substantially circular or other shapes, as described elsewhere herein. The mandrels **2** may be a solid or hollow wire or other cylindrical member having a diameter (or other cross-section) corresponding to the diameter of the lumen to be lined by the strip **24**, e.g., between about 0.005-0.300 inch (0.125-7.5 mm), 0.014-0.092 inch (0.35-2.3 mm), or 0.014-0.045 inch (0.35-1.15 mm). In an exemplary embodiment, the auxiliary mandrel **2***b* may have a substantially smaller diameter or other cross-section than the primary mandrel **2***a*. In exemplary embodiments, the mandrels **2** may be formed from beading or monofilament material, for example, lubricious material, e.g., PTFE or other fluoropolymer, silicone-treated Acetal, PTFE-coated stainless steel, Parylene-coated stainless steel, silver coated copper, and the like, having sufficient flexibility to allow the mandrels **2** to be wound onto a source reel **52** and/or onto a take-up reel (not shown) after being incorporated into a tubular body **8**.

Alternatively or in addition, the mandrels **2** may have a tubular liner predisposed about them, e.g. a fluoropolymer sleeve or coating or other tubular material which may facilitate removal of the mandrel **2** and/or be left behind upon removal of the mandrel **2** to form a liner. Further alternatively, a shim (not shown) may be positioned over a mandrel **2** and/or within a tubular or strip liner such that the shim (not shown) may facilitate creation of a lumen that is larger than the mandrel **2** with or without ultimate removal of the mandrel **2**. For example, a PTFE tube or strip shim (not shown) may be positioned around a mandrel **2** and inside of a strip or tubular liner. The mandrel/shim/liner assembly may then be incorporated into a braided shaft or finished apparatus. The shim (not shown) may be subsequently removed, e.g. after braiding, lamination, etc. to leave a lumen larger than the mandrel. After this, the mandrel may remain in place, for example in the case of the auxiliary mandrel **2***b* to serve as a pull wire, or simply removed with less force.

In an alternative embodiment, the mandrels **2** may be formed from material that substantially maintains its size and shape during fabrication of the tubular bodies, yet may be reduced in cross-section after fabrication to facilitate removal. For example, silver-coated copper wire, PTFE beading, or other malleable metals or polymers may be used for the mandrels **2** that, after fabrication of the tubular body **8**, may be necked down before and/or during removal. For example, after fabricating a tubular body **8**, the mandrels **2** (or the entire tubular body) may be pulled at one or both ends, thereby causing the mandrels **2** to plastically elongate and thereby reduce their outer cross-section slightly, which may reduce friction between the mandrels **2** and the surrounding liners, reinforcement members, and/or other materials, and thereby facilitate removal. Further alternatively, the mandrels **2** may include a rolled strip with inherent radial strength capable of supporting a lumen during braiding and/or lamination and/or other processing, but may subsequently be constrained, stretched, or otherwise removed. Further alternatively, the mandrels **2** may be constructed from material having relatively high thermal expansion such

that during heating, lamination, and/or reflow, the mandrels **2** expand and upon cooling contract, thereby creating a lumen larger than the original mandrel **2**.

In yet another alternative, the mandrels **2** may be formed from materials that may be dissolved, e.g., after fabrication, leaving the surrounding materials intact to define the lumens.

In still another alternative, tubular mandrels may be used that have sufficient hoop strength to resist deformation under the forces encountered during braiding and/or other fabrication and/or heating or other processing parameters experienced during fabrication. In this alternative, the tubular mandrels may remain substantially within the tubular bodies **8** after fabrication, e.g., to define the auxiliary lumen. For example, a relatively thick walled PTFE, a lined or bare polyimide tube, or other tubular mandrel may be used. Alternatively, the inner diameter of such a tubular mandrel may be temporarily supported by a temporary supporting mandrel (not shown), e.g. during braiding, and the temporary supporting mandrel may be removed prior to subsequent fabrication and/or heating or other processing steps, e.g., if the tubular mandrel is to remain as a permanent component of the tubular bodies.

Optionally, a source **54** of liner material **4** may be provided for the one or both mandrels **2**. For example, as shown, a source **54***a* of liner material **4***a* is provided such that the liner material **4***a* may be wrapped at least partially around the primary mandrel **2***a*, e.g., as the primary mandrel **2***a* and liner material **4***a* are fed through the guide **60**. The liner material **2***a* may be formed from lubricious material and/or may include one or more coatings (not shown) on an inner surface thereof oriented towards the primary mandrel **2***a*, which may provide an inner liner for a primary lumen of the resulting tubular bodies **8***a*.

For example, the liner material may include a base material, e.g., a relatively thin-walled polymer sheet having a width corresponding to the circumference of the corresponding mandrel, e.g., thermoplastics, such as polyether block amide, urethane, nylon, and the like, fluoropolymers, such as PTFE, FEP, TFE, and the like, thermoset, and thermoform plastics, such as polyimide or polyester, and the like. In exemplary embodiments, the liner material may have a thickness between about 0.0001-0.050 inch (0.0025-1.25 mm), 0.0001-0.003 inch (0.0025-0.076 mm), 0.0001-0.0015 inch (0.0025-0.038 mm), or 0.0005-0.002 inch (0.0125-0.05 mm).

Optionally, if desired a source of liner material may also be provided for the auxiliary mandrel **2***b* and/or for other auxiliary mandrels (not shown for simplicity). In this option, a guide (not shown) may be provided for wrapping the liner material around the auxiliary mandrel **2***b*, e.g., before the auxiliary mandrel **2***b* is positioned adjacent the primary mandrel **2***a*. In an alternative embodiment, tubular liner material may be provided on one or both mandrels s when loaded on the source **52**, and/or may be fed onto the desired mandrel in discrete segments (not shown) before passing the mandrels **2** through the guide **60** or horn gear **72**.

With additional reference to FIGS. **4**A and **4**B, the source **70** of reinforcement members **6** may provide one or more, e.g., a plurality of, reinforcement members **6** that may be wrapped around the mandrels **2**, e.g., upon exiting the guide **60**. In the exemplary embodiment shown in FIG. **4**B, the reinforcement source **70** may include an arrangement of horn gears **72**, e.g., mounted in a generally circular configuration around the guide **60**, for example, to a base or other support structure **76**. The horn gears **72** may be free to rotate about their individual central axes but may be substantially fixed translationally relative to one another and the guide **60**. The horn gears **72** may pass one or more carriers **74** of reinforcement members **6** around the path **78**, e.g., in a clockwise and/or counterclockwise direction, e.g., with at least some of the carriers travelling clockwise and some travelling counterclockwise, e.g., to create a braided pattern. The carriers **74** may be loaded onto the horn gears to create a variety of patterns, e.g., one-over-one-under (diamond pattern), two-over-two-under (herring bone pattern), one-over-one-under with two reinforcement members running side by side (tow), and/or other patterns, as are known in the art.

Alternatively, the horn gears **72** may be rotatable relative to the guide **60** and/or primary mandrel **2***a*, e.g., around a central axis of the guide **60**, e.g., along a path **78** shown in FIG. **4**B, while maintaining their same circular configuration, e.g., by rotating the base **76** relative to the guide **60**, as described further elsewhere herein.

In addition, the auxiliary mandrel **2***b* may be moved to different locations relative to the horn gears **72**, e.g., to position the auxiliary mandrel **2***b* relative to the primary mandrel **2***a* and/or reinforcement members **6**. For example, as shown in FIG. **4**B, during operation of the apparatus **50**, the source of auxiliary mandrel **2***b* may be positioned at locations A**1**, A**2**, or A**3**, e.g., for a predetermined time and/or distance along the primary mandrel **2***a*, and, as desired, moved to one of the other locations one or more times. Thus, in this manner, the location of the auxiliary mandrel **2***b* may be adjusted, which may result in the location of an auxiliary lumen defined by the auxiliary mandrel **2***b* being moved to desired locations, as shown in FIG. **4**C and as described elsewhere herein.

For example, in position A**1** shown in FIG. **4**A, one of the horn gears **72***a* may include a passage **73***a* therethrough, e.g., aligned with the central axis of the horn gear **72***a*, and the auxiliary mandrel **2***b* may pass through the passage **73***a*, e.g., from the source **52***b* towards the primary mandrel **2***a* where it exits the guide **60**. If liner material is wrapped or otherwise disposed around the auxiliary mandrel **2***b*, a guide (not shown) may be provided before, after, or within the passage **73***a* to wrap or otherwise dispose the liner material around the auxiliary mandrel **2***b*. Optionally, if additional auxiliary lumens are to be provided in the tubular bodies **8**, one or more additional horn gears may also include such passage(s) and/or guide(s) for guiding corresponding auxiliary mandrel(s) therethrough.

As described further below, in this location, the auxiliary mandrel **2***b* may be at least partially braided into the reinforcement members **6** adjacent the primary mandrel **2***a*, i.e., with some reinforcement members **6** surrounding both the primary mandrel **2***a* and the auxiliary mandrel **2***b*, and some reinforcement members **6** surrounding only the primary mandrel **2***a*, as identified by auxiliary mandrels A**1** shown in FIG. **4**C. By comparison, in location A**2**, i.e., with the auxiliary mandrel **2***b* directed immediately adjacent the primary mandrel **2***a*, e.g., through the guide **60**, all of the reinforcement members **6** may surround both the primary mandrel **2***a* and the auxiliary mandrel **2***b*, thereby positioning the auxiliary mandrel **2***b* closest to the primary mandrel **2***a* along the tubular device **8**. Finally, in location A**3**, i.e., with the auxiliary mandrel **2***b* outside the path of the horn gears **72**, e.g., outside the path **78** shown in FIG. **4**B, or otherwise directed towards the primary mandrel **2***a* after the braiding operation, all of the reinforcement members **6** may only surround the primary mandrel **2***a* and the auxiliary

mandrel **2***b* may remain outside all of the reinforcement members **6**, e.g., closest to the outer surface of the tubular device **8** shown in FIG. **4**C.

Optionally, if desired, individual carriers may be loaded with multiple reinforcement members (not shown), e.g., such that multiple reinforcement members are braided adjacent one another in each direction from each carrier. For example, with the auxiliary mandrel **2***b* directed from location A**1**, a first set of reinforcement members **43***a* may travel and be braided in a first direction by the horn gears **72** such that all of the windings of the first set **43***a* pass between the auxiliary mandrel **2***b* and the primary mandrel **2***a* at that specific horn gear. A second set of reinforcement members **43***b* may travel and be braided in a second opposite direction by the horn gears **72** such that all of the windings of the second set **43***b* pass over the auxiliary mandrel **2***b* at that specific horn gear. Otherwise, the reinforcement members may pass over and under one another according to the arrangement of horn gears **72** and carriers **74** loaded onto the reinforcement source **70**, which pattern generally alternates at each subsequent horn gear, e.g., as described in U.S. Publication No. 2014/0323964, incorporated by reference herein.

In addition, with the auxiliary mandrel **2***b* in position A**1**, one of the horn gears **72***a* may include a passage **73***a* therethrough, e.g., aligned with the central axis of the horn gear **72***a*, and the auxiliary mandrel **2***b* may pass through the passage **73***a*, e.g., from the source **52***b* towards the primary mandrel **2***a* where it exits the guide **60**. If liner material is wrapped or otherwise disposed around the auxiliary mandrel **2***b*, a guide (not shown) may be provided before, after, or within the passage **73***a* to wrap or otherwise dispose the liner material around the auxiliary mandrel **2***b*.

Optionally, if additional auxiliary lumens are to be provided in the tubular bodies **8**, one or more additional horn gears may also include such passage(s) and/or guide(s) for guiding corresponding auxiliary mandrel(s) therethrough, e.g., to provide auxiliary mandrel(s) in location A**1**, or additional auxiliary mandrel(s) may be provided at locations A**2** and/or A**3**, as desired.

With further reference to FIG. **4**A, as can be seen, the primary mandrel **2***a* may exit the guide **60** with the liner material **4***a* being wrapped substantially around the primary mandrel **2***a*. With the auxiliary mandrel **2***b* directed from the desired location, the auxiliary mandrel **2***b* may be directed towards the primary mandrel **2***a* such that the auxiliary mandrel **2***a* is disposed adjacent the primary mandrel **2***a*, e.g., before braiding (location A**2**), braided into the reinforcement members **6** (location A**1**), or after braiding (location A**3**).

At any time, the auxiliary mandrel **2***b* may be moved to a different location than its current one to transition the auxiliary mandrel **2***b* to the desired position relative to the primary mandrel **2***a* and/or reinforcement members **6**. Thus, in this manner, all of the reinforcement members **6** may surround the primary mandrel **2***a*, while all, some, or none of windings **43***a* may surround the auxiliary mandrel **2***b*, as shown in FIG. **4**C. This transition may be performed substantially continuously, e.g. by directing the auxiliary mandrel **2***b* to the desired location after a predetermined length or portion of the tubular device **7** has been braided in the desired manner. Alternatively, discrete lengths or portions may be braided in the desired manner, e.g., by stopping the apparatus **50**, removing and repositioning the auxiliary mandrel **2***b* to position the auxiliary mandrel **2***b* to the desired relative to the primary mandrel **2***a* and/or reinforcement members **6**, and then resuming operation for a desired time and/or length. This process may be repeated as many times as desired, e.g., to produce tubular devices, such as the apparatus **10**A, **10**B shown in FIGS. **2** and **3**.

Returning to FIGS. **4**A and **4**B, the drive mechanism **80** may include one or more components for pulling or otherwise directing the mandrels **2** through the apparatus **50**. For example, the drive mechanism **80** may include a pair of spaced-apart rollers **82** coupled to a motor (not shown) that engage the reinforcement-wrapped mandrels **2** and apply sufficient tension to pull the mandrels **2** from their sources **52** through the guide **60** and/or horn gear **72***a* while the reinforcement members **6** are braided around the mandrels **2**. Alternatively, the drive mechanism may be provided before the reinforcement members **6** are braided around the mandrels **2**, e.g., pushing the primary mandrel **2***a* through the braiding operation and potentially pulling the auxiliary mandrel **2***b* by the braiding action itself. Optionally, other drive mechanisms and/or tension adjusters (not shown) may be provided for maintaining a desired tension and/or otherwise guiding the mandrels **2**, liners **4**, reinforcement members **6**, and assembled device in a desired manner along the fabrication path.

Optionally, as shown in FIG. **4**A, the jacket source **90** may be provided for applying one or more layers of jacket material around the reinforcement-wrapped mandrels **2**. For example, a co-extruder, laminator, or other applicator may be provided that applies melted, uncured, and/or otherwise raw jacket material **7**, e.g., from a hopper or other container (not shown), or rolls sheets of jacket material **7** may be wrapped around the reinforcement members **43** and mandrels **2**. For example, for thermoplastic or other flowable materials, a heater (not shown) within a co-extruder may melt or otherwise soften the jacket material **7** to allow the jacket material **7** to flow around the reinforcement members **43** and into contact with the liner material **4** surrounding the mandrels **2** (or the mandrels **2** directly if no liner material is provided). Alternatively, the jacket material **7** may be a thermoset plastic or other material such that components of the jacket material **7** may be delivered into the co-extruder, e.g., as a liquid, powder, and the like, and mixed to form a slurry that is delivered around the reinforcement-wrapped mandrels **2**. The components may chemically or otherwise react with one another and/or be heat fused to form a solid jacket **7** once cured. Exemplary materials for the jacket material **7** include plastics, e.g., thermoplastics, such as polyether block amide, nylon, or urethanes, thermoset plastics, metals, or composite materials. Alternatively, other processing may be used to bond or otherwise attach the jacket material **7** to the liner material **4** and/or embed the reinforcement members **43** in the jacket material **7**, thereby resulting in an integral tubular body **8**.

The resulting tubular body **8** (with or without jacket material **7**) may be collected, e.g., on a capture reel or in a container (not shown). Thereafter, the tubular body **8** may be further processed to make a catheter, sheath, or other device. For example, a cutter or other tool (not shown) may separate the tubular body **8** into individual tubular shafts, e.g., before or after removing the mandrels **2**. For example, the mandrels **2** may remain within the tubular body **8** when cut into individual devices, and then may be removed, resulting in a primary lumen and an auxiliary lumen, e.g., similar to the apparatus **10** shown in FIG. **1**B. Alternatively, if the friction between the mandrels **2** and the surrounding material is relatively low, the mandrels **2** may be removed before the tubular body **8** is cut into individual devices.

The resulting inner surface **41***a* of the primary lumen **18***a* may have a substantially uniform cross-section, e.g., as

shown in FIG. **1**B. Similar the auxiliary lumen **18***b* may also have a substantially uniform cross-section, e.g., also as shown in FIG. **1**B or may have a variable cross-section, if desired (not shown).

Other components may be added to the individual tubular devices, as desired for the particular application. For example, for a steerable catheter, such as the apparatus **110** shown in FIG. **5**, a steering element **136** may be inserted through the auxiliary lumen **118***b* (created when the auxiliary mandrel **2***b* is removed). In an alternative embodiment, the auxiliary mandrel **2***b* may remain within the tubular device to provide the steering element, e.g., if the friction between the outer surface of the auxiliary mandrel **2***b* and the liner or other material defining the auxiliary lumen are relatively low. A tip or other component (not shown) may be attached to a distal end **114** of the apparatus **110**, e.g., after attaching the distal end **136***b* of the steering element **136** to the tip. The other end of the steering element may be coupled to an actuator of a handle attached to a proximal end of the tubular device, e.g., similar to the embodiment shown in FIG. **1**A and described elsewhere herein.

For the apparatus **210** shown in FIG. **6**, the auxiliary lumen **218***b* may be formed by positioning the auxiliary mandrel **2***b* in location A**2** (shown in FIGS. **4**B and **4**C or optionally in location A**1** for at least some portions) and generally braiding the reinforcement material **6** around both the primary and auxiliary mandrels **2***a*, **2***b*, except that at the segments corresponding to the locations of the electrodes **238**, the auxiliary mandrel **2***b* may be moved to location A**3** and then returned back to location A**2** (or A**1**). After the outer layer **244** has been applied around the reinforcement members **242**, the mandrels may be removed to provide an auxiliary lumen with segments **218***b*-**1** braided into or under the reinforcement layer **242** other than segments **218***b*-**2** at the electrode locations.

One or more wires **236** may be directed into the auxiliary lumen **218***b* (or may be used as the auxiliary mandrel, if desired), and the segments **218***b*-**2** may be accessed, e.g., by cutting into the outer layer **244** to expose the wire(s), which may then be coupled to the electrodes **238** mounted on the apparatus **210**.

Alternatively, the auxiliary mandrel **2***b* may remain at location A**2** (or A**1**) for the entire length of the tubular body **8**, and a segment of the auxiliary mandrel **2***b* may be manually (or automatically) pulled out from within the braid of the reinforcement members **6**, as shown in FIG. **7**A before applying the outer layer **244**. In this alternative, the auxiliary lumen **318***b* may be discontinuous, i.e., communicating with side openings **319**. One or more wire(s) may be directed into the auxiliary lumen **318***b* such that regions of the wire(s) exit and reenter the side openings **319**. These regions may then be exposed and/or otherwise coupled to an electrode (not shown) mounted on the apparatus **310**.

Turning to FIGS. **8**A and **8**B, optionally, in any of the embodiments herein, the size of the auxiliary lumen **418***b* may be varied at desired locations along the apparatus **410**, e.g., by using an auxiliary mandrel having a variable diameter or other cross-section (not shown). For example, in the apparatus **410** shown in FIG. **8**A, an auxiliary lumen **318***b* is provided adjacent a central lumen **318***a*, which may be positioned relative to the central lumen **318***a* and/or reinforcement members (not shown), similar to other embodiments herein. As shown, the auxiliary lumen **418***b* includes a first or proximal segment **318***b*-**1** having a first diameter and extending from a side opening **319** along a portion of the apparatus **410**. The auxiliary lumen **418***b* then transitions to a second segment **418***b*-**2** having a second diameter smaller than the first diameter.

Such an auxiliary lumen **418***b* may be formed using an auxiliary mandrel having regions corresponding to the first and second diameters and lengths of the segments. As shown in FIG. **8**B, a steering element **436** may be provided that has similar diameters and regions (e.g., slightly smaller than the first and second diameters). After removing the auxiliary mandrel, the steering element **436** may be loaded into the auxiliary lumen **418***b* through the side opening **419** and the distal segment (not shown) may be coupled to the distal end of the apparatus **410**, similar to other embodiments herein. Alternatively, the auxiliary mandrel itself may be used as the steering element, also similar to other embodiments herein. This configuration may enhance pushability of the apparatus **410**, e.g., since the proximal, larger segment may be relatively stiffer than the distal, smaller segment.

Optionally, in any of the embodiments herein, one or more stiffening members may be added to desired portions of the apparatus. For example, FIGS. **9**A and **9**B show an exemplary embodiment of an apparatus **510** including a central lumen **518***a* and auxiliary lumen **518***b*, which may be surrounded and/or braided into a reinforcement layer **542**, similar to other embodiments herein.

Unlike previous embodiments, a pair of stiffening members **536** have also been braided into the reinforcement layer **542**. For example, with reference to the apparatus **50** in FIGS. **4**A-**4**C, at desired portions of the tubular body **8**, one or more stiffening members (not shown) may be directed adjacent the primary mandrel **2***a*, e.g., at positions similar to A**1** (to braid the stiffening members into the reinforcement members **6**. In this manner, the supported portion(s) may have greater column strength than other unsupported portions of the resulting apparatus **510**.

Turning to FIGS. **10**-**11**J, an exemplary method for making a steerable catheter **610** (best seen in FIG. **11**J) that generally includes a proximal end **612**, a distal end **614**, and one or more lumens **616** extending therebetween, similar to other embodiments herein. For example, as shown in FIG. **11**J, the catheter **610** includes a central or primary lumen **616***a* and a pair of steering lumens **616***b* slidably receiving respective pull wires **636** coupled to a pull wire ring **638** adjacent the distal end **614**. The catheter **610** may be fabricated using similar materials and methods to the previous embodiments, e.g., using a braiding apparatus, similar to that shown in FIGS. **4**A and **4**B.

For example, turning to FIG. **10**, a mandrel/reinforcement subassembly **640** may be made by braiding a plurality of reinforcement members **643** around a primary mandrel **2***a* and at least partially around a pair of secondary mandrels **2***b*, e.g., with the location of the secondary mandrels **2***b* being changed in a predetermined manner along the length of the subassembly **640**. In the exemplary embodiment shown, along a first portion **640***a* of the subassembly **640**, e.g., corresponding to an intermediate and/or proximal portion of the catheter **610**, the secondary mandrels **2***b* are braided into the reinforcement members **643**, e.g., such that some of the members **643** are disposed between the primary and secondary mandrels **2***a*, **2***b*, and some members surround both the primary and secondary mandrels **2***a*, **2***b*, as shown in FIG. **10**A.

At a second portion **640***b*, e.g., corresponding to a distal portion of the catheter **610**, the secondary mandrels **2***b* transition such all of the reinforcement members **643** are braided around only the primary mandrel **2***a*, as shown in

FIG. **10**B. Braiding of the reinforcement members **643** may continue beyond the ends of the secondary mandrels **2***b*, e.g., as shown in FIG. **10**C.

One or more outer layers may then be applied around the subassembly **640** to provide the final catheter **610**. For example, as shown in FIG. **11**A, a plurality of tubular jackets **650** may be applied around the subassembly **640**, e.g., having different materials and/or mechanical properties, as desired for the different portions of the catheter **610**. The jackets **650** may be sized to have the subassembly **640** inserted into them such that they abut or are otherwise disposed adjacent one another around the subassembly **640**. In addition, a tubular jacket and/or shim **652** (where at least the outer part of the shim **652** is ultimately removable) may be positioned around the subassembly **640**, e.g., around the portion **640***b* such that the shim **652** at least partially covers the unconstrained ends of the secondary mandrels **2***b*.

Subsequently, the resulting assembly **660** may be reflowed, heated, and/or otherwise laminated, e.g., similar to other embodiments described elsewhere herein. The shim **652** may then be removed, as shown in FIG. **11**C, and then the mandrels **2***b* may also be removed, as shown in FIGS. **11**D and **11**E. As shown in FIG. **11**E, a shoulder **664** (at the right of the assembly **660**) remains at the junction between the tubular jackets **650** and the removed shim **652** with the lumens **616***b* created by removal of the secondary mandrels **2***b* exiting from the face of the shoulder **664** in a position radially outward from the reinforcement members **643** present in the portion **640***b*.

Turning to FIG. **11**F, a pull wire ring **638** having pull wires **636** extending from its proximal edge may then be inserted over the portion **640***b* with the pull wires **636** may be loaded into the lumens **616***b*. For example, distal ends **636***b* of the pull wires **636** may be attached to the proximal edge of the ring **638**, e.g., by welding, soldering, bonding with adhesive, and the like before the ring **638** is inserted over the portion **640***b*. This allows the pull wires **636** to be inserted into the auxiliary lumens **616***b* (not shown in FIG. **11**F; see, e.g., FIG. **11**E) without taking a substantial bend and the pull wire ring **638** may abut the shoulder **664**.

As shown in FIG. **11**G, the reinforcement members **643** may then be trimmed at or near the distal edge of the pull wire ring **638** with the pull wire ring constraining the reinforcement members **643** such that, as shown in FIG. **11**I, a subsequent a jacket and or tip may be bonded, laminated, reflowed or otherwise attached over and/or beyond the pull wire ring **638** without risk of the reinforcement members **643** rising to or protruding through the surface. Using this method, tip defects may be minimized, stress on the pull wire may be minimized, and/or the assembly may be otherwise considerably improved.

Optionally, the pull wire ring **638** may include one or more features (e.g., holes, slots, etc. not shown) to enhance attachment to the catheter shaft, tip, etc. In addition or alternatively, a thermoplastic liner (e.g., with a coating, similar to other embodiments herein) may be provided on the distal end to enable discrete tip sections to be added and subsequently laminated creating a highly manufacturable device with a completely contiguous/welded liner surface with no edges, discontinuities, or potential for delamination, skiving, leakage, and the like.

Configuring the ring **638** and/or tip jacket components in this manner may provide one or more advantages. For example, lapping the braid or reinforcement layer into and through the ring **638** may eliminate a common kink point that may be a limitation with current devices. In addition, this configuration may eliminate problems with cut end wire protrusions as they are full constrained within the ring **638**. In addition, this configuration may provide locations for pull wire lumens that substantially align with desired positions of pull wires, which may ease assembly, enhance integrity of the tip, and/or improve alignment of pull forces.

With reference to the previous embodiments, it will be appreciated that lumens and/or mandrels used to create them as described may be replaced by wires, conductors, optical fibers, axial reinforcing elements, e.g., aramid fibers, UHMWPE, or other axial elements. in order to incorporate such elements into the catheter construction for the purpose achieving desired mechanical or functional performance.

The foregoing disclosure of the exemplary embodiments has been presented for purposes of illustration and description. It is not intended to be exhaustive or to limit the invention to the precise forms disclosed. Many variations and modifications of the embodiments described herein will be apparent to one of ordinary skill in the art in light of the above disclosure.

Further, in describing representative embodiments, the specification may have presented the method and/or process as a particular sequence of steps. However, to the extent that the method or process does not rely on the particular order of steps set forth herein, the method or process should not be limited to the particular sequence of steps described. As one of ordinary skill in the art would appreciate, other sequences of steps may be possible. Therefore, the particular order of the steps set forth in the specification should not be construed as limitations on the claims.

While the invention is susceptible to various modifications, and alternative forms, specific examples thereof have been shown in the drawings and are herein described in detail. It should be understood, however, that the invention is not to be limited to the particular forms or methods disclosed, but to the contrary, the invention is to cover all modifications, equivalents and alternatives falling within the scope of the appended claims.

We claim:

**1**. A tubular device for a catheter or sheath comprising a proximal end and a distal end sized for introduction into a patient's body, the tubular device comprising:

a central lumen extending between the proximal end and the distal end;

an auxiliary lumen extending at least partially between the proximal end and the distal end adjacent the central lumen;

one or more reinforcement members comprising windings extending helically around the central lumen between the proximal end and the distal end; and

one or more layers surrounding the one or more reinforcement members,

wherein the tubular device comprises a first portion in which at least some of the windings pass between the central lumen and the auxiliary lumen and at least some of the windings surround both the central lumen and the auxiliary lumen, and a second portion in which either a) all of the windings surround both the central lumen and the auxiliary lumen or b) all of the windings surround the central lumen and the auxiliary lumen is disposed outside the windings.

**2**. The tubular device of claim **1**, wherein along the second portion all of the windings surround both the central lumen and the auxiliary lumen.

**3**. The tubular device of claim **2**, wherein the tubular device further comprises a third portion adjacent the second portion in which a) at least some of the windings pass between the central and auxiliary lumens and at least some

of the windings surround both the central lumen and the auxiliary lumen, or b) all of the windings surround the central lumen and the auxiliary lumen is disposed outside the windings.

**4**. The tubular device of claim **1**, wherein along the second portion all of the windings surround the central lumen and the auxiliary lumen is disposed outside the windings.

**5**. The tubular device of claim **4**, wherein the tubular device further comprises a third portion adjacent the second portion in which a) at least some of the windings pass between the central lumen and the auxiliary lumen and at least some of the windings surround both the central lumen and the auxiliary lumen, or b) all of the windings surround both the central lumen and the auxiliary lumen.

**6**. An apparatus for performing a procedure within a patient's body, comprising:

a tubular member comprising a proximal end, a distal end sized for introduction into the patient's body, a central axis extending therebetween, and a distal portion extending distally from an intermediate portion to the distal end;

a primary lumen extending between the proximal end and the distal end and surrounding at least a portion of the central axis;

a steering element lumen extending at least partially between the proximal end and the distal end adjacent the primary lumen;

a steering element slidably disposed within the steering element lumen and comprising a distal end fixed to the tubular member distal end and a proximal end adjacent the proximal end of the tubular member;

an actuator on the proximal end coupled to the steering element proximal end such that, actuation of the actuator applies axial tension or compression to the steering element, thereby causing the distal portion to bend;

one or more reinforcement members comprising windings extending around the primary lumen between the proximal end and the distal end; and

one or more layers surrounding the one or more reinforcement members,

wherein the tubular member comprises a first portion in which at least some of the windings pass between the primary lumen and the steering element lumen and at least some of the windings surrounding both the primary lumen and the steering element lumen, and a second portion in which either a) all of the windings surround both the primary lumen and the steering element lumen or b) all of the windings surround the primary lumen and the steering element lumen is disposed outside the windings.

**7**. The apparatus of claim **6**, wherein along the second portion all of the windings surround both the central lumen and the auxiliary lumen.

**8**. The apparatus of claim **7**, wherein the tubular device further comprises a third portion adjacent the second portion in which a) at least some of the windings pass between the primary lumen and the steering element lumen and at least some of the windings surround both the primary lumen and the steering element lumen, or b) all of the windings surround the primary lumen and the steering element lumen is disposed outside the windings.

**9**. The apparatus of claim **6**, wherein along the second portion all of the windings surround the primary lumen and the steering element lumen is disposed outside the windings.

**10**. The apparatus of claim **9**, wherein the tubular device further comprises a third portion adjacent the second portion in which a) at least some of the windings pass between the primary lumen and the steering element lumen and at least some of the windings surround both the primary lumen and the steering element lumen, or b) all of the windings surround both the primary lumen and the steering element lumen.

**11**. The apparatus of claim **6**, wherein the first portion is the distal portion of the tubular member and the second portion is at least a portion of the intermediate portion of the tubular member.

**12**. The apparatus of claim **6**, wherein the central lumen is defined by a liner comprising an inner surface substantially surrounding the central lumen.

**13**. The apparatus of claim **6**, wherein the steering element lumen is defined by a liner comprising an inner surface substantially surrounding the steering element lumen.

**14**. The apparatus of claim **6**, wherein the steering element lumen is smaller than the primary lumen.

**15**. The apparatus of claim **6**, wherein the primary lumen is substantially aligned around a central longitudinal axis extending between the proximal end and the distal end, and wherein the steering element lumen is offset radially from the central axis.

**16**. The apparatus of claim **6**, further comprising one or more treatment or diagnostic elements on the distal portion.

**17**. The apparatus of claim **6**, wherein the primary lumen communicates with an outlet in the distal end.

**18**. The apparatus of claim **6**, further comprising one or more sensors or electrodes on the distal portion.

**19**. The apparatus of claim **18**, further comprising one or more conductors extending through the primary lumen from the tubular member proximal end to the distal portion and coupled to the one or more sensors or electrodes.

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